Supreme Court, U.S.
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IN THE

Supreme Court of the United States

JOAN E. JACKSON,

Petitioner,

v.

*THE HONORABLE JOHN MCHUGH,
SECRETARY OF THE ARMY,
[THE HONORABLE PETER GEREN,
SECRETARY OF THE ARMY,]

Respondent,

v.

BRIANNA SKINNER-HARRIS,

Movant.

ON PETITION FOR WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS FOR
THE FOURTH CIRCUIT

SUPPLEMENTAL APPENDIX

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* Sept. 21, 2009 Appointment.

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APPENDIX B

A COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENT FOR DRUG DISCOVERY AND BIODIVERSITY CONSERVATION IN AFRICA

[selected sections re Quest. Presented II]

[Original in Exhibit 6, Dist. Ct. Dkt. 60, signed by "Authorized Business Official," Director, Walter Reed Army Institute of Research, Col. August J. Salvado, on 21 July 1994 [page 9], and Petitioner, as Associate Program Leader [page 10]; and both signed on "Statement of Intent To Establish a Consortium Agreement" [unnumbered page 12]; *see* §§ 8.04 Exhibit 6 [Dkt. 60] and 11.6 [page A-10, Exhibit 3, Dkt. 25] stating: "*patent rights, data and publication, and liability shall survive the termination or expiration of this agreement...*" (emphasis added); both latter sections copied below.]

Article 1. Background

1.00 This agreement is entered into under the authority of the Federal Technology Transfer Act of 1986, 15 U.S.C. 3710a, *et seq.*, between the signatory parties to this Agreement, and is in furtherance of the International Cooperative Biodiversity Groups (ICBG) Program jointly sponsored by the Fogarty International Center of the National Institutes of Health, the National Science Foundation and the United States Agency for International Development.

1.02 The members of the ICBG entitled "Drug Development and Conservation of Biodiversity in West and Central Africa" desire to enter into an agreement in which Intellectual Property of the ICBG is properly protected, utilized, and compensated...

2.03 "Subject Data" means all recorded information first produced in the performance of this Agreement, including the following which are provided as examples and not intended as limitations: species inventories, ethnobiology, phytochemistry, drug development data, and published works, catalogues, and databases referring to such information produced or compiled as part of the activities of the members of the ICBG.

2.04 "Intellectual Property Rights of the ICBG" (IPR) means any and all rights relating to natural products, processes and information regarding natural products discovered, obtained or invented in the course of activities of the parties in furtherance of this Agreement, and includes but is not limited to, for example: utility patents, plant breeder patents, petty patents, trade secrets, copyright, trademark. IPR includes any other statutory or common law or traditional rights, other than real property and personal property, which may be obtained or enforced in any legal jurisdiction of the world.

4.01 Title to IPR. The WRAIR agrees to manage all IPR consistent with its agreement with Fogarty International Center and this Agreement, specifically the royalty sharing provisions contained in Article 4.03 below...

4.03 Royalty Sharing

4.03.1 Twenty percent (20%) of all royalty and other considerations generated from licenses of IPR shall be equitably divided among those parties contributing intellectually to the creation of the IPR taking into account their relative contribution and ensuring that the inventors in each case receive not less than fifteen percent (15%).

4.03.2 Fifty percent (50%) of all royalty income and other considerations generated from licenses of IPR shall be donated to the Bioresurces Development and Conservation Program (BDCP). All royalty income generated from licenses of IPR and donated to the BDCP shall be used by BDCP solely for programs and projects designed to promote sustainable economic development relating to biodiversity conservation in Nigeria and Cameroon. An independent Trust Fund shall be established as outlined in the attached Compensation and Benefit Sharing Plan for this purpose. [See, last four pages Exhibit 6 Dkt. 60, the BDCP Trust Fund was established.]

4.03.3 Thirty percent (30%) of all royalty income and other considerations generated from licenses of IPR shall be donated to a Tropical Disease Drug Development Program based in WRAIR to be used exclusively for development of tropical disease drugs.

4.08 Copyright. Copyright in works by the parties and compilations of information, including catalogues and databases, by the parties shall be

protected by use of copyright notices and registration, where appropriate.

8.04 The rights and duties specified in provisions of this Agreement covering Intellectual Property Rights, Subject Data, Proprietary Information, Royalty-Sharing, and Liability –No Warranty shall survive the termination or expiration of this Agreement.

APPENDIX C

Constitutional and Statutory Provisions

- **U.S. Const. art. III, § 2, cl. 1-2:**

The judicial power [of one supreme Court] shall extend to all Cases, in law and equity, arising under this Constitution, the laws of the United States, and Treaties made, or which shall be made, under their authority;...-to controversies to which the United States shall be a party;...In all other cases before mentioned, the supreme Court shall have appellate jurisdiction, both as to law and fact...

- **U.S. Const. amend. I:**

Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof; or abridging the freedom of speech, or of the press; or the right of the people peaceably to assemble, and to petition the Government for a redress of grievances.

- **U.S. Const. amend. V:**

No person shall be held to answer for a capital, or otherwise infamous crime, unless on presentment or indictment of a Grand Jury, except in cases arising in the land or naval forces, or in the Militia, when actual service in time of War or public danger; nor shall any person be subject for the same offense to be twice put in

jeopardy of life or limb; nor shall be compelled to be a witness against himself, nor be deprived of life, liberty, or property, without due process of law; nor shall private property be taken for public use, without just compensation.

- **U.S. Const. amend. XIV, § 1:**

All persons born or naturalized in the United States, and subject to the jurisdiction thereof, are citizens of the Unites States and of the State wherein they reside. No State shall make or enforce any law which shall abridge the privileges or immunities of citizens of the United States; nor shall any State deprive any person of life, liberty, or property, without due process of law; nor deny to any person within its jurisdiction the equal protection of the laws.

- **Freedom of Information Act, 5 U.S.C. § 552 (2009).**

§ 552. Public information; agency rules, opinions, orders, records, and proceedings.

(a) Each agency shall make available to the public information as follows:

(1) Each agency shall separately state and currently publish in the Federal Register for the guidance of the public--

(A) descriptions of its central and field organization and the established places at which, the employees (and in the case of a uniformed service, the members) from whom, and the methods whereby, the public may obtain information, make submittals or requests, or obtain decisions;

(B) statements of the general course and method by which its functions are channeled and determined, including the nature and requirements of all formal and informal procedures available;

(C) rules of procedure, descriptions of forms available or the places at which forms may be obtained, and instructions as to the scope and contents of all papers, reports, or examinations;

(D) substantive rules of general applicability adopted as authorized by law, and statements of general policy or interpretations of general applicability formulated and adopted by the agency; and

(E) each amendment, revision, or repeal of the foregoing.

Except to the extent that a person has actual and timely notice of the terms thereof, a person may not in any manner be required to resort to, or be adversely affected by, a matter required to be published in the Federal Register and not so published. For the purpose of this paragraph, matter reasonably available to the class of persons affected thereby is deemed published in the Federal Register when incorporated by reference therein with the approval of the Director of the Federal Register.

(2) Each agency, in accordance with published rules, shall make available for public inspection and copying--

(A) final opinions, including concurring and dissenting opinions, as well as orders, made in the adjudication of cases;

(B) those statements of policy and interpretations which have been adopted by the agency and are not published in the Federal Register;

(C) administrative staff manuals and instructions to staff that affect a member of the public;

(D) copies of all records, regardless of form or format, which have been released to any person under paragraph (3) and which, because of the nature of their subject matter, the agency determines have become or are likely to become the subject of subsequent requests for substantially the same records; and

(E) a general index of the records referred to under subparagraph (D);

unless the materials are promptly published and copies offered for sale. For records created on or after November 1, 1996, within one year after such date, each agency shall make such records available, including by computer telecommunications or, if computer telecommunications means have not been established by the agency, by other electronic means. To the extent required to prevent a clearly unwarranted invasion of personal privacy, an agen-

cy may delete identifying details when it makes available or publishes an opinion, statement of policy, interpretation, staff manual, instruction, or copies of records referred to in subparagraph (D). However, in each case the justification for the deletion shall be explained fully in writing, and the extent of such deletion shall be indicated on the portion of the record which is made available or published, unless including that indication would harm an interest protected by the exemption in subsection (b) under which the deletion is made. If technically feasible, the extent of the deletion shall be indicated at the place in the record where the deletion was made. Each agency shall also maintain and make available for public inspection and copying current indexes providing identifying information for the public as to any matter issued, adopted, or promulgated after July 4, 1967, and required by this paragraph to be made available or published. Each agency shall promptly publish, quarterly or more frequently, and distribute (by sale or otherwise) copies of each index or supplements thereto unless it determines by order published in the Federal Register that the publication would be unnecessary and impracticable, in which case the agency shall nonetheless provide copies of such index on request at a cost not to exceed the direct cost of duplication. Each agency shall make the index referred to in subparagraph (E) available by computer telecommunications by December 31, 1999. A final order, opinion, statement of policy, interpretation, or staff manual or instruction that affects a member of the public may be relied on, used, or cited as precedent by an agency against a party other than an agency only if--

(i) it has been indexed and either made available or published as provided by this paragraph; or

(ii) the party has actual and timely notice of the terms thereof.

(3)(A) Except with respect to the records made available under paragraphs (1) and (2) of this subsection, and except as provided in subparagraph (E), each agency, upon any request for records which (i) reasonably describes such records and (ii) is made in accordance with published rules stating the time, place, fees (if any), and procedures to be followed, shall make the records promptly available to any person.

(B) In making any record available to a person under this paragraph, an agency shall provide the record in any form or format requested by the person if the record is readily reproducible by the agency in that form or format. Each agency shall make reasonable efforts to maintain its records in forms or formats that are reproducible for purposes of this section.

(C) In responding under this paragraph to a request for records, an agency shall make reasonable efforts to search for the records in electronic form or format, except when such efforts would significantly interfere with the operation of the agency's automated information system.

(D) For purposes of this paragraph, the term "search" means to review, manually or by automated means, agency records for the purpose of lo-

cating those records which are responsive to a request.

(E) An agency, or part of an agency, that is an element of the intelligence community (as that term is defined in section 3(4) of the National Security Act of 1947 (50 U.S.C. 401a(4))) shall not make any record available under this paragraph to--

(i) any government entity, other than a State, territory, commonwealth, or district of the United States, or any subdivision thereof; or

(ii) a representative of a government entity described in clause (i).

(4)(A)(i) In order to carry out the provisions of this section, each agency shall promulgate regulations, pursuant to notice and receipt of public comment, specifying the schedule of fees applicable to the processing of requests under this section and establishing procedures and guidelines for determining when such fees should be waived or reduced. Such schedule shall conform to the guidelines which shall be promulgated, pursuant to notice and receipt of public comment, by the Director of the Office of Management and Budget and which shall provide for a uniform schedule of fees for all agencies.

(ii) Such agency regulations shall provide that--

(I) fees shall be limited to reasonable standard charges for document search, duplication, and review, when records are requested for commercial use;

(II) fees shall be limited to reasonable standard charges for document duplication when records are not sought for commercial use and the request is made by an educational or noncommercial scientific institution, whose purpose is scholarly or scientific research; or a representative of the news media; and

(III) for any request not described in (I) or (II), fees shall be limited to reasonable standard charges for document search and duplication.

In this clause, the term "a representative of the news media" means any person or entity that gathers information of potential interest to a segment of the public, uses its editorial skills to turn the raw materials into a distinct work, and distributes that work to an audience. In this clause, the term "news" means information that is about current events or that would be of current interest to the public. Examples of news-media entities are television or radio stations broadcasting to the public at large and publishers of periodicals (but only if such entities qualify as disseminators of "news") who make their products available for purchase by or subscription by or free distribution to the general public. These examples are not all-inclusive. Moreover, as methods of news delivery evolve (for example, the adoption of the electronic dissemination of newspapers through telecommunications services), such alternative media shall be considered to be news-media entities. A freelance journalist shall be regarded as working for a news-media entity if the journalist can demonstrate a solid basis for expecting publication through that entity, whether or not the journalist is actually employed by the entity. A

publication contract would present a solid basis for such an expectation; the Government may also consider the past publication record of the requester in making such a determination.

(iii) Documents shall be furnished without any charge or at a charge reduced below the fees established under clause (ii) if disclosure of the information is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government and is not primarily in the commercial interest of the requester.

(iv) Fee schedules shall provide for the recovery of only the direct costs of search, duplication, or review. Review costs shall include only the direct costs incurred during the initial examination of a document for the purposes of determining whether the documents must be disclosed under this section and for the purposes of withholding any portions exempt from disclosure under this section. Review costs may not include any costs incurred in resolving issues of law or policy that may be raised in the course of processing a request under this section. No fee may be charged by any agency under this section--

(I) if the costs of routine collection and processing of the fee are likely to equal or exceed the amount of the fee; or

(II) for any request described in clause (ii)(II) or (III) of this subparagraph for the first two hours of search time or for the first one hundred pages of duplication.

(v) No agency may require advance payment of any fee unless the requester has previously failed to pay fees in a timely fashion, or the agency has determined that the fee will exceed $250.

(vi) Nothing in this subparagraph shall supersede fees chargeable under a statute specifically providing for setting the level of fees for particular types of records.

(vii) In any action by a requester regarding the waiver of fees under this section, the court shall determine the matter de novo: *Provided*, That the court's review of the matter shall be limited to the record before the agency.

(viii) An agency shall not assess search fees (or in the case of a requester described under clause (ii)(II), duplication fees) under this subparagraph if the agency fails to comply with any time limit under paragraph (6), if no unusual or exceptional circumstances (as those terms are defined for purposes of paragraphs (6)(B) and (C), respectively) apply to the processing of the request.

(B) On complaint, the district court of the United States in the district in which the complainant resides, or has his principal place of business, or in which the agency records are situated, or in the District of Columbia, has jurisdiction to enjoin the agency from withholding agency records and to order the production of any agency records improperly withheld from the complainant. In such a case the court shall determine the matter de novo, and may examine the contents of such agency records in camera to determine whether such records or any

part thereof shall be withheld under any of the exemptions set forth in subsection (b) of this section, and the burden is on the agency to sustain its action. In addition to any other matters to which a court accords substantial weight, a court shall accord substantial weight to an affidavit of an agency concerning the agency's determination as to technical feasibility under paragraph (2)(C) and subsection (b) and reproducibility under paragraph (3)(B).

(C) Notwithstanding any other provision of law, the defendant shall serve an answer or otherwise plead to any complaint made under this subsection within thirty days after service upon the defendant of the pleading in which such complaint is made, unless the court otherwise directs for good cause shown.

[**(D)** Repealed. Pub.L. 98-620, Title IV, § 402(2), Nov. 8, 1984, 98 Stat. 3357]

(E)(i) The court may assess against the United States reasonable attorney fees and other litigation costs reasonably incurred in any case under this section in which the complainant has substantially prevailed.

(ii) For purposes of this subparagraph, a complainant has substantially prevailed if the complainant has obtained relief through either--

(I) a judicial order, or an enforceable written agreement or consent decree; or

(II) a voluntary or unilateral change in position by the agency, if the complainant's claim is not insubstantial.

(F)(i) Whenever the court orders the production of any agency records improperly withheld from the complainant and assesses against the United States reasonable attorney fees and other litigation costs, and the court additionally issues a written finding that the circumstances surrounding the withholding raise questions whether agency personnel acted arbitrarily or capriciously with respect to the withholding, the Special Counsel shall promptly initiate a proceeding to determine whether disciplinary action is warranted against the officer or employee who was primarily responsible for the withholding. The Special Counsel, after investigation and consideration of the evidence submitted, shall submit his findings and recommendations to the administrative authority of the agency concerned and shall send copies of the findings and recommendations to the officer or employee or his representative. The administrative authority shall take the corrective action that the Special Counsel recommends.

(ii) The Attorney General shall--

(I) notify the Special Counsel of each civil action described under the first sentence of clause (i); and

(II) annually submit a report to Congress on the number of such civil actions in the preceding year.

(iii) The Special Counsel shall annually submit a report to Congress on the actions taken by the Special Counsel under clause (i).

(G) In the event of noncompliance with the order of the court, the district court may punish for contempt the responsible employee, and in the case of a uniformed service, the responsible member.

(5) Each agency having more than one member shall maintain and make available for public inspection a record of the final votes of each member in every agency proceeding.

(6)(A) Each agency, upon any request for records made under paragraph (1), (2), or (3) of this subsection, shall--

(i) determine within 20 days (excepting Saturdays, Sundays, and legal public holidays) after the receipt of any such request whether to comply with such request and shall immediately notify the person making such request of such determination and the reasons therefor, and of the right of such person to appeal to the head of the agency any adverse determination; and

(ii) make a determination with respect to any appeal within twenty days (excepting Saturdays, Sundays, and legal public holidays) after the receipt of such appeal. If on appeal the denial of the request for records is in whole or in part upheld, the agency shall notify the person making such request of the provisions for judicial review of that determination under paragraph (4) of this subsection.

The 20-day period under clause (i) shall commence on the date on which the request is first received by the appropriate component of the agency, but in any event not later than ten days after the request is first received by any component of the agency that is designated in the agency's regulations under this section to receive requests under this section. The 20-day period shall not be tolled by the agency except--

(I) that the agency may make one request to the requester for information and toll the 20-day period while it is awaiting such information that it has reasonably requested from the requester under this section; or

(II) if necessary to clarify with the requester issues regarding fee assessment. In either case, the agency's receipt of the requester's response to the agency's request for information or clarification ends the tolling period.

(B)(i) In unusual circumstances as specified in this subparagraph, the time limits prescribed in either clause (i) or clause (ii) of subparagraph (A) may be extended by written notice to the person making such request setting forth the unusual circumstances for such extension and the date on which a determination is expected to be dispatched. No such notice shall specify a date that would result in an extension for more than ten working days, except as provided in clause (ii) of this subparagraph.

(ii) With respect to a request for which a written notice under clause (i) extends the time limits

prescribed under clause (i) of subparagraph (A), the agency shall notify the person making the request if the request cannot be processed within the time limit specified in that clause and shall provide the person an opportunity to limit the scope of the request so that it may be processed within that time limit or an opportunity to arrange with the agency an alternative time frame for processing the request or a modified request. To aid the requester, each agency shall make available its FOIA Public Liaison, who shall assist in the resolution of any disputes between the requester and the agency. Refusal by the person to reasonably modify the request or arrange such an alternative time frame shall be considered as a factor in determining whether exceptional circumstances exist for purposes of subparagraph (C).

(iii) As used in this subparagraph, "unusual circumstances" means, but only to the extent reasonably necessary to the proper processing of the particular requests--

(I) the need to search for and collect the requested records from field facilities or other establishments that are separate from the office processing the request;

(II) the need to search for, collect, and appropriately examine a voluminous amount of separate and distinct records which are demanded in a single request; or

(III) the need for consultation, which shall be conducted with all practicable speed, with

another agency having a substantial interest in the determination of the request or among two or more components of the agency having substantial subject-matter interest therein.

(iv) Each agency may promulgate regulations, pursuant to notice and receipt of public comment, providing for the aggregation of certain requests by the same requestor, or by a group of requestors acting in concert, if the agency reasonably believes that such requests actually constitute a single request, which would otherwise satisfy the unusual circumstances specified in this subparagraph, and the requests involve clearly related matters. Multiple requests involving unrelated matters shall not be aggregated.

(C)(i) Any person making a request to any agency for records under paragraph (1), (2), or (3) of this subsection shall be deemed to have exhausted his administrative remedies with respect to such request if the agency fails to comply with the applicable time limit provisions of this paragraph. If the Government can show exceptional circumstances exist and that the agency is exercising due diligence in responding to the request, the court may retain jurisdiction and allow the agency additional time to complete its review of the records. Upon any determination by an agency to comply with a request for records, the records shall be made promptly available to such person making such request. Any notification of denial of any request for records under this subsection shall set forth the names and titles or positions of each person responsible for the denial of such request.

(ii) For purposes of this subparagraph, the term "exceptional circumstances" does not include a delay that results from a predictable agency workload of requests under this section, unless the agency demonstrates reasonable progress in reducing its backlog of pending requests.

(iii) Refusal by a person to reasonably modify the scope of a request or arrange an alternative time frame for processing a request (or a modified request) under clause (ii) after being given an opportunity to do so by the agency to whom the person made the request shall be considered as a factor in determining whether exceptional circumstances exist for purposes of this subparagraph.

(D)(i) Each agency may promulgate regulations, pursuant to notice and receipt of public comment, providing for multitrack processing of requests for records based on the amount of work or time (or both) involved in processing requests.

(ii) Regulations under this subparagraph may provide a person making a request that does not qualify for the fastest multitrack processing an opportunity to limit the scope of the request in order to qualify for faster processing.

(iii) This subparagraph shall not be considered to affect the requirement under subparagraph (C) to exercise due diligence.

(E)(i) Each agency shall promulgate regulations, pursuant to notice and receipt of public comment, providing for expedited processing of requests for records--

(I) in cases in which the person requesting the records demonstrates a compelling need; and

(II) in other cases determined by the agency.

(ii) Notwithstanding clause (i), regulations under this subparagraph must ensure--

(I) that a determination of whether to provide expedited processing shall be made, and notice of the determination shall be provided to the person making the request, within 10 days after the date of the request; and

(II) expeditious consideration of administrative appeals of such determinations of whether to provide expedited processing.

(iii) An agency shall process as soon as practicable any request for records to which the agency has granted expedited processing under this subparagraph. Agency action to deny or affirm denial of a request for expedited processing pursuant to this subparagraph, and failure by an agency to respond in a timely manner to such a request shall be subject to judicial review under paragraph (4), except that the judicial review shall be based on the record before the agency at the time of the determination.

(iv) A district court of the United States shall not have jurisdiction to review an agency denial of expedited processing of a request for records after the agency has provided a complete response to the request.

(v) For purposes of this subparagraph, the term "compelling need" means--

(I) that a failure to obtain requested records on an expedited basis under this paragraph could reasonably be expected to pose an imminent threat to the life or physical safety of an individual; or

(II) with respect to a request made by a person primarily engaged in disseminating information, urgency to inform the public concerning actual or alleged Federal Government activity.

(vi) A demonstration of a compelling need by a person making a request for expedited processing shall be made by a statement certified by such person to be true and correct to the best of such person's knowledge and belief.

(F) In denying a request for records, in whole or in part, an agency shall make a reasonable effort to estimate the volume of any requested matter the provision of which is denied, and shall provide any such estimate to the person making the request, unless providing such estimate would harm an interest protected by the exemption in subsection (b) pursuant to which the denial is made.

(7) Each agency shall--

(A) establish a system to assign an individualized tracking number for each request received that will take longer than ten days to process and provide to each person making a request the tracking number assigned to the request; and

(B) establish a telephone line or Internet service that provides information about the status of a request to the person making the request using the assigned tracking number, including--

(i) the date on which the agency originally received the request; and

(ii) an estimated date on which the agency will complete action on the request.

(b) This section does not apply to matters that are--

(1) (A) specifically authorized under criteria established by an Executive order to be kept secret in the interest of national defense or foreign policy and (B) are in fact properly classified pursuant to such Executive order;

(2) related solely to the internal personnel rules and practices of an agency;

(3) specifically exempted from disclosure by statute (other than section 552b of this title), if that statute--

(A)(i) requires that the matters be withheld from the public in such a manner as to leave no discretion on the issue; or

(ii) establishes particular criteria for withholding or refers to particular types of matters to be withheld; and

(B) if enacted after the date of enactment of the OPEN FOIA Act of 2009, specifically cites to this paragraph.

(4) trade secrets and commercial or financial information obtained from a person and privileged or confidential;

(5) inter-agency or intra-agency memorandums or letters which would not be available by law to a party other than an agency in litigation with the agency;

(6) personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy;

(7) records or information compiled for law enforcement purposes, but only to the extent that the production of such law enforcement records or information (A) could reasonably be expected to interfere with enforcement proceedings, (B) would deprive a person of a right to a fair trial or an impartial adjudication, (C) could reasonably be expected to constitute an unwarranted invasion of personal privacy, (D) could reasonably be expected to disclose the identity of a confidential source, including a State, local, or foreign agency or authority or any private institution which furnished information on a confidential basis, and, in the case of a record or information compiled by criminal law enforcement authority in the course of a criminal investigation or by an agency conducting a lawful national security intelligence investigation, information furnished by a confidential source, (E) would disclose techniques and pro-

cedures for law enforcement investigations or prosecutions, or would disclose guidelines for law enforcement investigations or prosecutions if such disclosure could reasonably be expected to risk circumvention of the law, or (F) could reasonably be expected to endanger the life or physical safety of any individual;

(8) contained in or related to examination, operating, or condition reports prepared by, on behalf of, or for the use of an agency responsible for the regulation or supervision of financial institutions; or

(9) geological and geophysical information and data, including maps, concerning wells.

Any reasonably segregable portion of a record shall be provided to any person requesting such record after deletion of the portions which are exempt under this subsection. The amount of information deleted, and the exemption under which the deletion is made, shall be indicated on the released portion of the record, unless including that indication would harm an interest protected by the exemption in this subsection under which the deletion is made. If technically feasible, the amount of the information deleted, and the exemption under which the deletion is made, shall be indicated at the place in the record where such deletion is made.

(c)(1) Whenever a request is made which involves access to records described in subsection (b)(7)(A) and--

(A) the investigation or proceeding involves a possible violation of criminal law; and

(B) there is reason to believe that (i) the subject of the investigation or proceeding is not aware of its pendency, and (ii) disclosure of the existence of the records could reasonably be expected to interfere with enforcement proceedings, the agency may, during only such time as that circumstance continues, treat the records as not subject to the requirements of this section.

(2) Whenever informant records maintained by a criminal law enforcement agency under an informant's name or personal identifier are requested by a third party according to the informant's name or personal identifier, the agency may treat the records as not subject to the requirements of this section unless the informant's status as an informant has been officially confirmed.

(3) Whenever a request is made which involves access to records maintained by the Federal Bureau of Investigation pertaining to foreign intelligence or counterintelligence, or international terrorism, and the existence of the records is classified information as provided in subsection (b)(1), the Bureau may, as long as the existence of the records remains classified information, treat the records as not subject to the requirements of this section.

(d) This section does not authorize withholding of information or limit the availability of records to the public, except as specifically stated in this section. This section is not authority to withhold information from Congress.

(e)(1) On or before February 1 of each year, each agency shall submit to the Attorney General of the United States a report which shall cover the preceding fiscal year and which shall include--

(A) the number of determinations made by the agency not to comply with requests for records made to such agency under subsection (a) and the reasons for each such determination;

(B)(i) the number of appeals made by persons under subsection (a)(6), the result of such appeals, and the reason for the action upon each appeal that results in a denial of information; and

(ii) a complete list of all statutes that the agency relies upon to authorize the agency to withhold information under subsection (b)(3), the number of occasions on which each statute was relied upon, a description of whether a court has upheld the decision of the agency to withhold information under each such statute, and a concise description of the scope of any information withheld;

(C) the number of requests for records pending before the agency as of September 30 of the preceding year, and the median and average number of days that such requests had been pending before the agency as of that date;

(D) the number of requests for records received by the agency and the number of requests which the agency processed;

(E) the median number of days taken by the agency to process different types of requests,

based on the date on which the requests were received by the agency;

(F) the average number of days for the agency to respond to a request beginning on the date on which the request was received by the agency, the median number of days for the agency to respond to such requests, and the range in number of days for the agency to respond to such requests;

(G) based on the number of business days that have elapsed since each request was originally received by the agency--

(i) the number of requests for records to which the agency has responded with a determination within a period up to and including 20 days, and in 20-day increments up to and including 200 days;

(ii) the number of requests for records to which the agency has responded with a determination within a period greater than 200 days and less than 301 days;

(iii) the number of requests for records to which the agency has responded with a determination within a period greater than 300 days and less than 401 days; and

(iv) the number of requests for records to which the agency has responded with a determination within a period greater than 400 days;

(H) the average number of days for the agency to provide the granted information beginning on the

date on which the request was originally filed, the median number of days for the agency to provide the granted information, and the range in number of days for the agency to provide the granted information;

(I) the median and average number of days for the agency to respond to administrative appeals based on the date on which the appeals originally were received by the agency, the highest number of business days taken by the agency to respond to an administrative appeal, and the lowest number of business days taken by the agency to respond to an administrative appeal;

(J) data on the 10 active requests with the earliest filing dates pending at each agency, including the amount of time that has elapsed since each request was originally received by the agency;

(K) data on the 10 active administrative appeals with the earliest filing dates pending before the agency as of September 30 of the preceding year, including the number of business days that have elapsed since the requests were originally received by the agency;

(L) the number of expedited review requests that are granted and denied, the average and median number of days for adjudicating expedited review requests, and the number adjudicated within the required 10 days;

(M) the number of fee waiver requests that are granted and denied, and the average and median

number of days for adjudicating fee waiver determinations;

(N) the total amount of fees collected by the agency for processing requests; and

(O) the number of full-time staff of the agency devoted to processing requests for records under this section, and the total amount expended by the agency for processing such requests.

(2) Information in each report submitted under paragraph (1) shall be expressed in terms of each principal component of the agency and for the agency overall.

(3) Each agency shall make each such report available to the public including by computer telecommunications, or if computer telecommunications means have not been established by the agency, by other electronic means. In addition, each agency shall make the raw statistical data used in its reports available electronically to the public upon request.

(4) The Attorney General of the United States shall make each report which has been made available by electronic means available at a single electronic access point. The Attorney General of the United States shall notify the Chairman and ranking minority member of the Committee on Government Reform and Oversight of the House of Representatives and the Chairman and ranking minority member of the Committees on Governmental Affairs and the Judiciary of the Senate, no later than April 1 of the year in which each such report is is-

sued, that such reports are available by electronic means.

(5) The Attorney General of the United States, in consultation with the Director of the Office of Management and Budget, shall develop reporting and performance guidelines in connection with reports required by this subsection by October 1, 1997, and may establish additional requirements for such reports as the Attorney General determines may be useful.

(6) The Attorney General of the United States shall submit an annual report on or before April 1 of each calendar year which shall include for the prior calendar year a listing of the number of cases arising under this section, the exemption involved in each case, the disposition of such case, and the cost, fees, and penalties assessed under subparagraphs (E), (F), and (G) of subsection (a)(4). Such report shall also include a description of the efforts undertaken by the Department of Justice to encourage agency compliance with this section.

(f) For purposes of this section, the term--

(1) "agency" as defined in section 551(1) of this title includes any executive department, military department, Government corporation, Government controlled corporation, or other establishment in the executive branch of the Government (including the Executive Office of the President), or any independent regulatory agency; and

(2) "record" and any other term used in this section in reference to information includes--

(A) any information that would be an agency record subject to the requirements of this section when maintained by an agency in any format, including an electronic format; and

(B) any information described under subparagraph (A) that is maintained for an agency by an entity under Government contract, for the purposes of records management.

(g) The head of each agency shall prepare and make publicly available upon request, reference material or a guide for requesting records or information from the agency, subject to the exemptions in subsection (b), including--

(1) an index of all major information systems of the agency;

(2) a description of major information and record locator systems maintained by the agency; and

(3) a handbook for obtaining various types and categories of public information from the agency pursuant to chapter 35 of title 44, and under this section.

(h)(1) There is established the Office of Government Information Services within the National Archives and Records Administration.

(2) The Office of Government Information Services shall--

(A) review policies and procedures of administrative agencies under this section;

(B) review compliance with this section by administrative agencies; and

(C) recommend policy changes to Congress and the President to improve the administration of this section.

(3) The Office of Government Information Services shall offer mediation services to resolve disputes between persons making requests under this section and administrative agencies as a non-exclusive alternative to litigation and, at the discretion of the Office, may issue advisory opinions if mediation has not resolved the dispute.

(i) The Government Accountability Office shall conduct audits of administrative agencies on the implementation of this section and issue reports detailing the results of such audits.

(j) Each agency shall designate a Chief FOIA Officer who shall be a senior official of such agency (at the Assistant Secretary or equivalent level).

(k) The Chief FOIA Officer of each agency shall, subject to the authority of the head of the agency--

(1) have agency-wide responsibility for efficient and appropriate compliance with this section;

(2) monitor implementation of this section throughout the agency and keep the head of the agency, the chief legal officer of the agency, and the Attorney General appropriately informed of the agency's performance in implementing this section;

(3) recommend to the head of the agency such adjustments to agency practices, policies, personnel, and funding as may be necessary to improve its implementation of this section;

(4) review and report to the Attorney General, through the head of the agency, at such times and in such formats as the Attorney General may direct, on the agency's performance in implementing this section;

(5) facilitate public understanding of the purposes of the statutory exemptions of this section by including concise descriptions of the exemptions in both the agency's handbook issued under subsection (g), and the agency's annual report on this section, and by providing an overview, where appropriate, of certain general categories of agency records to which those exemptions apply; and

(6) designate one or more FOIA Public Liaisons.

(l) FOIA Public Liaisons shall report to the agency Chief FOIA Officer and shall serve as supervisory officials to whom a requester under this section can raise concerns about the service the requester has received from the FOIA Requester Center, following an initial response from the FOIA Requester Center Staff. FOIA Public Liaisons shall be responsible for assisting in reducing delays, increasing transparency and understanding of the status of requests, and assisting in the resolution of disputes.

- **Administrative Procedure Act of 1993, 5 U.S.C. § 706 (2009).**

§ 706. Scope of review

To the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action. The reviewing court shall—

(1) compel agency action unlawfully withheld or unreasonably delayed; and

(2) hold unlawful and set aside agency action, findings, and conclusions found to be--

(A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;

(B) contrary to constitutional right, power, privilege, or immunity;

(C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right;

(D) without observance of procedure required by law;

(E) unsupported by substantial evidence in a case subject to sections 556 and 557 of this title or otherwise reviewed on the record of an agency hearing provided by statute; or

(F) unwarranted by the facts to the extent that the facts are subject to trial *de novo* by the reviewing court.

In making the foregoing determinations, the court shall review the whole record or those parts of it cited by a party, and due account shall be taken of the rule of prejudicial error.

- **Federal Technology Transfer Act of 1986, 15 U.S.C. §§ 3710(a) and 3710a (2009).**

§ 3710. Utilization of Federal technology

(a) Policy

(1) It is the continuing responsibility of the Federal Government to ensure the full use of the results of the Nation's Federal investment in research and development. To this end the Federal Government shall strive where appropriate to transfer federally owned or originated technology to State and local governments and to the private sector.

(2) Technology transfer, consistent with mission responsibilities, is a responsibility of each laboratory science and engineering professional.

(3) Each laboratory director shall ensure that efforts to transfer technology are considered positively in laboratory job descriptions, employee promotion policies, and evaluation of the job performance of scientists and engineers in the laboratory....

§ 3710a. Cooperative research and development agreements

(a) General authority

Each Federal agency may permit the director of any of its Government-operated Federal laboratories, and, to the extent provided in an agency-approved joint work statement or, if permitted by the agency, in an agency-approved annual strategic plan, the director of any of its Government-owned, contractor-operated laboratories--

(1) to enter into cooperative research and development agreements on behalf of such agency (subject to subsection (c) of this section) with other Federal agencies; units of State or local government; industrial organizations (including corporations, partnerships, and limited partnerships, and industrial development organizations); public and private foundations; nonprofit organizations (including universities); or other persons (including licensees of inventions owned by the Federal agency); and

(2) to negotiate licensing agreements under section 207 of Title 35, or under other authorities (in the case of a Government-owned, contractor-operated laboratory, subject to subsection (c) of this section) for inventions made or other intellectual property developed at the laboratory and other inventions or other intellectual property that may be voluntarily assigned to the Government.

(b) Enumerated authority

(1) Under an agreement entered into pursuant to subsection (a)(1) of this section, the laboratory may grant, or agree to grant in advance, to a collaborating party patent licenses or assignments, or options thereto, in any invention made in whole or in part by a laboratory employee under the agreement, or, subject to section 209 of Title 35, may grant a license to an invention which is federally owned, for which a patent application was filed before the signing of the agreement, and directly within the scope of the work under the agreement, for reasonable compensation when appropriate. The laboratory shall ensure, through such agreement, that the collaborating party has the option to choose an exclusive license for a pre-negotiated field of use for any such invention under the agreement or, if there is more than one collaborating party, that the collaborating parties are offered the option to hold licensing rights that collectively encompass the rights that would be held under such an exclusive license by one party. In consideration for the Government's contribution under the agreement, grants under this paragraph shall be subject to the following explicit conditions:

(A) A nonexclusive, nontransferable, irrevocable, paid-up license from the collaborating party to the laboratory to practice the invention or have the invention practiced throughout the world by or on behalf of the Government. In the exercise of such license, the Government shall not publicly disclose trade secrets or commercial or financial information that is privileged or confidential within the meaning of section 552(b)(4) of Title 5 or

which would be considered as such if it had been obtained from a non-Federal party.
(B) If a laboratory assigns title or grants an exclusive license to such an invention, the Government shall retain the right--

(i) to require the collaborating party to grant to a responsible applicant a nonexclusive, partially exclusive, or exclusive license to use the invention in the applicant's licensed field of use, on terms that are reasonable under the circumstances; or

(ii) if the collaborating party fails to grant such a license, to grant the license itself.

(C) The Government may exercise its right retained under subparagraph (B) only in exceptional circumstances and only if the Government determines that--

(i) the action is necessary to meet health or safety needs that are not reasonably satisfied by the collaborating party;

(ii) the action is necessary to meet requirements for public use specified by Federal regulations, and such requirements are not reasonably satisfied by the collaborating party; or

(iii) the collaborating party has failed to comply with an agreement containing provisions described in subsection (c)(4)(B) of this section.

This determination is subject to administrative appeal and judicial review under section 203(2) of Title 35.

(2) Under agreements entered into pursuant to subsection (a)(1) of this section, the laboratory shall ensure that a collaborating party may retain title to any invention made solely by its employee in exchange for normally granting the Government a nonexclusive, nontransferable, irrevocable, paid-up license to practice the invention or have the invention practiced throughout the world by or on behalf of the Government for research or other Government purposes.

(3) Under an agreement entered into pursuant to subsection (a)(1) of this section, a laboratory may--

(A) accept, retain, and use funds, personnel, services, and property from a collaborating party and provide personnel, services, and property to a collaborating party;

(B) use funds received from a collaborating party in accordance with subparagraph (A) to hire personnel to carry out the agreement who will not be subject to full-time-equivalent restrictions of the agency;

(C) to the extent consistent with any applicable agency requirements or standards of conduct, permit an employee or former employee of the laboratory to participate in an effort to commercialize an invention made by the employee or former employee while in the employment or service of the Government; and

(D) waive, subject to reservation by the Government of a nonexclusive, irrevocable, paid-up license to practice the invention or have the invention practiced throughout the world by or on behalf of the Government, in advance, in whole or in part, any right of ownership which the Federal Government may have to any subject invention made under the agreement by a collaborating party or employee of a collaborating party.

(4) A collaborating party in an exclusive license in any invention made under an agreement entered into pursuant to subsection (a)(1) of this section shall have the right of enforcement under chapter 29 of Title 35.

(5) A Government-owned, contractor-operated laboratory that enters into a cooperative research and development agreement pursuant to subsection (a)(1) of this section may use or obligate royalties or other income accruing to the laboratory under such agreement with respect to any invention only--

(A) for payments to inventors;

(B) for purposes described in clauses (i), (ii), (iii), and (iv) of section 3710c(a)(1)(B) of this title; and

(C) for scientific research and development consistent with the research and development missions and objectives of the laboratory.

(6)(A) In the case of a laboratory that is part of the National Nuclear Security Administration, a designated official of that Administration may waive any

license retained by the Government under paragraph (1)(A), (2), or (3)(D), in whole or in part and according to negotiated terms and conditions, if the designated official finds that the retention of the license by the Government would substantially inhibit the commercialization of an invention that would otherwise serve an important national security mission.

(B) The authority to grant a waiver under subparagraph (A) shall expire on the date that is five years after October 30, 2000. The expiration under the preceding sentence of authority to grant a waiver under subparagraph (A) shall not affect any waiver granted under that subparagraph before the expiration of such authority.

(C) Not later than February 15 of each year, the Administrator for Nuclear Security shall submit to Congress a report on any waivers granted under this paragraph during the preceding year.

(c) Contract considerations

(1) A Federal agency may issue regulations on suitable procedures for implementing the provisions of this section; however, implementation of this section shall not be delayed until issuance of such regulations.

(2) The agency in permitting a Federal laboratory to enter into agreements under this section shall be guided by the purposes of this chapter.

(3)(A) Any agency using the authority given it under subsection (a) of this section shall review stan-

dards of conduct for its employees for resolving potential conflicts of interest to make sure they adequately establish guidelines for situations likely to arise through the use of this authority, including but not limited to cases where present or former employees or their partners negotiate licenses or assignments of titles to inventions or negotiate cooperative research and development agreements with Federal agencies (including the agency with which the employee involved is or was formerly employed).

(B) If, in implementing subparagraph (A), an agency is unable to resolve potential conflicts of interest within its current statutory framework, it shall propose necessary statutory changes to be forwarded to its authorizing committees in Congress.

(4) The laboratory director in deciding what cooperative research and development agreements to enter into shall--

(A) give special consideration to small business firms, and consortia involving small business firms; and

(B) give preference to business units located in the United States which agree that products embodying inventions made under the cooperative research and development agreement or produced through the use of such inventions will be manufactured substantially in the United States and, in the case of any industrial organization or other person subject to the control of a foreign company or government, as appropriate, take into consideration whether or not such foreign government

permits United States agencies, organizations, or other persons to enter into cooperative research and development agreements and licensing agreements.

(5)(A) If the head of the agency or his designee desires an opportunity to disapprove or require the modification of any such agreement presented by the director of a Government-operated laboratory, the agreement shall provide a 30- day period within which such action must be taken beginning on the date the agreement is presented to him or her by the head of the laboratory concerned.

(B) In any case in which the head of an agency or his designee disapproves or requires the modification of an agreement presented by the director of a Government-operated laboratory under this section, the head of the agency or such designee shall transmit a written explanation of such disapproval or modification to the head of the laboratory concerned.

(C)(i) Any non-Federal entity that operates a laboratory pursuant to a contract with a Federal agency shall submit to the agency any cooperative research and development agreement that the entity proposes to enter into and the joint work statement if required with respect to that agreement.

(ii) A Federal agency that receives a proposed agreement and joint work statement under clause (i) shall review and approve, request specific modifications to, or disapprove the proposed agreement and joint work statement within 30 days after such submission. No agreement may be entered into by a Government-owned, contractor-operated laboratory

under this section before both approval of the agreement and approval of a joint work statement under this clause.

(iii) In any case in which an agency which has contracted with an entity referred to in clause (i) disapproves or requests the modification of a cooperative research and development agreement or joint work statement submitted under that clause, the agency shall transmit a written explanation of such disapproval or modification to the head of the laboratory concerned.

(iv) Any agency that has contracted with a non-Federal entity to operate a laboratory may develop and provide to such laboratory one or more model cooperative research and development agreements for purposes of standardizing practices and procedures, resolving common legal issues, and enabling review of cooperative research and development agreements to be carried out in a routine and prompt manner.

(v) A Federal agency may waive the requirements of clause (i) or (ii) under such circumstances as the agency considers appropriate.

(6) Each agency shall maintain a record of all agreements entered into under this section.

(7)(A) No trade secrets or commercial or financial information that is privileged or confidential, under the meaning of section 552(b)(4) of Title 5, which is obtained in the conduct of research or as a result of activities under this chapter from a non-Federal

party participating in a cooperative research and development agreement shall be disclosed.

(B) The director, or in the case of a contractor-operated laboratory, the agency, for a period of up to 5 years after development of information that results from research and development activities conducted under this chapter and that would be a trade secret or commercial or financial information that is privileged or confidential if the information had been obtained from a non-Federal party participating in a cooperative research and development agreement, may provide appropriate protections against the dissemination of such information, including exemption from subchapter II of chapter 5 of Title 5.

(d) Definitions

As used in this section--

(1) the term "cooperative research and development agreement" means any agreement between one or more Federal laboratories and one or more non-Federal parties under which the Government, through its laboratories, provides personnel, services, facilities, equipment, intellectual property, or other resources with or without reimbursement (but not funds to non-Federal parties) and the non-Federal parties provide funds, personnel, services, facilities, equipment, intellectual property, or other resources toward the conduct of specified research or development efforts which are consistent with the missions of the laboratory; except that such term does not include a procurement contract or cooperative agreement as

those terms are used in sections 6303, 6304, and 6305 of Title 31;

(2) the term "laboratory" means--

(A) a facility or group of facilities owned, leased, or otherwise used by a Federal agency, a substantial purpose of which is the performance of research, development, or engineering by employees of the Federal Government;

(B) a group of Government-owned, contractor-operated facilities (including a weapon production facility of the Department of Energy) under a common contract, when a substantial purpose of the contract is the performance of research and development, or the production, maintenance, testing, or dismantlement of a nuclear weapon or its components, for the Federal Government; and

(C) a Government-owned, contractor-operated facility (including a weapon production facility of the Department of Energy) that is not under a common contract described in subparagraph (B), and the primary purpose of which is the performance of research and development, or the production, maintenance, testing, or dismantlement of a nuclear weapon or its components, for the Federal Government, but such term does not include any facility covered by Executive Order No. 12344, dated February 1, 1982, pertaining to the naval nuclear propulsion program;

(3) the term "joint work statement" means a proposal prepared for a Federal agency by the director of a Government-owned, contractor-operated laboratory describing the purpose and scope of a proposed cooperative research and development agreement, and assigning rights and responsibilities among the agency, the laboratory, and any other party or parties to the proposed agreement; and

(4) the term "weapon production facility of the Department of Energy" means a facility under the control or jurisdiction of the Secretary of Energy that is operated for national security purposes and is engaged in the production, maintenance, testing, or dismantlement of a nuclear weapon or its components.

(e) Determination of laboratory missions

For purposes of this section, an agency shall make separate determinations of the mission or missions of each of its laboratories.

(f) Relationship to other laws

Nothing in this section is intended to limit or diminish existing authorities of any agency.

(g) Principles

In implementing this section, each agency which has contracted with a non-Federal entity to operate a laboratory shall be guided by the following principles:

(1) The implementation shall advance program missions at the laboratory, including any national security mission.

(2) Classified information and unclassified sensitive information protected by law, regulation, or Executive order shall be appropriately safeguarded.

- **17 U.S.C. § 105 (2009).**

Copyright protection under this title is not available for any work of the United States Government, but the United States Government is not precluded from receiving or holding copyrights transferred to it by assignment, bequest, or otherwise.

- **18 U.S.C. § 208 (2009).**

§ 208. Acts affecting a personal financial interest

(a) Except as permitted by subsection (b) hereof, whoever, being an officer or employee of the executive branch of the United States Government, or of any independent agency of the United States, a Federal Reserve bank director, officer, or employee, or an officer or employee of the District of Columbia, including a special Government employee, participates personally and substantially as a Government officer or employee, through decision, approval, disapproval, recommendation, the rendering of advice, investigation, or otherwise, in a judi-

cial or other proceeding, application, request for a ruling or other determination, contract, claim, controversy, charge, accusation, arrest, or other particular matter in which, to his knowledge, he, his spouse, minor child, general partner, organization in which he is serving as officer, director, trustee, general partner or employee, or any person or organization with whom he is negotiating or has any arrangement concerning prospective employment, has a financial interest--

Shall be subject to the penalties set forth in section 216 of this title.

(b) Subsection (a) shall not apply--

(1) if the officer or employee first advises the Government official responsible for appointment to his or her position of the nature and circumstances of the judicial or other proceeding, application, request for a ruling or other determination, contract, claim, controversy, charge, accusation, arrest, or other particular matter and makes full disclosure of the financial interest and receives in advance a written determination made by such official that the interest is not so substantial as to be deemed likely to affect the integrity of the services which the Government may expect from such officer or employee;

(2) if, by regulation issued by the Director of the Office of Government Ethics, applicable to all or a portion of all officers and employees covered by this section, and published in the Federal Register, the financial interest has been exempted from the requirements of subsection (a) as being too

remote or too inconsequential to affect the integrity of the services of the Government officers or employees to which such regulation applies;

(3) in the case of a special Government employee serving on an advisory committee within the meaning of the Federal Advisory Committee Act (including an individual being considered for an appointment to such a position), the official responsible for the employee's appointment, after review of the financial disclosure report filed by the individual pursuant to the Ethics in Government Act of 1978, certifies in writing that the need for the individual's services outweighs the potential for a conflict of interest created by the financial interest involved; or

(4) if the financial interest that would be affected by the particular matter involved is that resulting solely from the interest of the officer or employee, or his or her spouse or minor child, in birthrights-

(A) in an Indian tribe, band, nation, or other organized group or community, including any Alaska Native village corporation as defined in or established pursuant to the Alaska Native Claims Settlement Act, which is recognized as eligible for the special programs and services provided by the United States to Indians because of their status as Indians,

(B) in an Indian allotment the title to which is held in trust by the United States or which is inalienable by the allottee without the consent of the United States, or

(C) in an Indian claims fund held in trust or administered by the United States,

if the particular matter does not involve the Indian allotment or claims fund or the Indian tribe, band, nation, organized group or community, or Alaska Native village corporation as a specific party or parties.

(c)(1) For the purpose of paragraph (1) of subsection (b), in the case of class A and B directors of Federal Reserve banks, the Board of Governors of the Federal Reserve System shall be deemed to be the Government official responsible for appointment.

(2) The potential availability of an exemption under any particular paragraph of subsection (b) does not preclude an exemption being granted pursuant to another paragraph of subsection (b).

(d)(1) Upon request, a copy of any determination granting an exemption under subsection (b)(1) or (b)(3) shall be made available to the public by the agency granting the exemption pursuant to the procedures set forth in section 105 of the Ethics in Government Act of 1978. In making such determination available, the agency may withhold from disclosure any information contained in the determination that would be exempt from disclosure under section 552 of title 5. For purposes of determinations under subsection (b)(3), the information describing each financial interest shall be no more extensive than that required of the individual in his or her financial disclosure report under the Ethics in Government Act of 1978.

(2) The Office of Government Ethics, after consultation with the Attorney General, shall issue uniform regulations for the issuance of waivers and exemptions under subsection (b) which shall--

(A) list and describe exemptions; and

(B) provide guidance with respect to the types of interests that are not so substantial as to be deemed likely to affect the integrity of the services the Government may expect from the employee.

- **18 U.S.C. § 209 (2009).**

§ 209. Salary of Government officials and employees payable only by United States

(a) Whoever receives any salary, or any contribution to or supplementation of salary, as compensation for his services as an officer or employee of the executive branch of the United States Government, of any independent agency of the United States, or of the District of Columbia, from any source other than the Government of the United States, except as may be contributed out of the treasury of any State, county, or municipality; or

Whoever, whether an individual, partnership, association, corporation, or other organization pays, makes any contribution to, or in any way supplements, the salary of any such officer or employee under circumstances which would make its receipt a violation of this subsection--

Shall be subject to the penalties set forth in section 216 of this title.

(b) Nothing herein prevents an officer or employee of the executive branch of the United States Government, or of any independent agency of the United States, or of the District of Columbia, from continuing to participate in a bona fide pension, retirement, group life, health or accident insurance, profit-sharing, stock bonus, or other employee welfare or benefit plan maintained by a former employer.

(c) This section does not apply to a special Government employee or to an officer or employee of the Government serving without compensation, whether or not he is a special Government employee, or to any person paying, contributing to, or supplementing his salary as such.

(d) This section does not prohibit payment or acceptance of contributions, awards, or other expenses under the terms of chapter 41 of title 5.

(e) This section does not prohibit the payment of actual relocation expenses incident to participation, or the acceptance of same by a participant in an executive exchange or fellowship program in an executive agency: *Provided*, That such program has been established by statute or Executive order of the President, offers appointments not to exceed three hundred and sixty-five days, and permits no extensions in excess of ninety additional days or, in the case of participants in overseas assignments, in excess of three hundred and sixty-five days.

(f) This section does not prohibit acceptance or receipt, by any officer or employee injured during the commission of an offense described in section 351 or 1751 of this title, of contributions or payments from an organization which is described in section 501(c)(3) of the Internal Revenue Code of 1986 and which is exempt from taxation under section 501(a) of such Code.

(g)(1) This section does not prohibit an employee of a private sector organization, while assigned to an agency under chapter 37 of title 5, from continuing to receive pay and benefits from such organization in accordance with such chapter.

(2) For purposes of this subsection, the term "agency" means an agency (as defined by section 3701 of title 5) and the Office of the Chief Technology Officer of the District of Columbia.

(h) This section does not prohibit a member of the reserve components of the armed forces on active duty pursuant to a call or order to active duty under a provision of law referred to in section 101(a)(13) of title 10 from receiving from any person that employed such member before the call or order to active duty any payment of any part of the salary or wages that such person would have paid the member if the member's employment had not been interrupted by such call or order to active duty.

- **28 U.S.C. § 1254(1):**

Cases in the court of appeals may be reviewed by the Supreme Court by the following methods: (1) By writ of certiorari granted upon petition of any party to any civil or criminal case, before or after rendition of judgment or decree....

- **28 U.S.C. § 1291 (2009)**
Final decisions of district courts

The courts of appeals (other than the United States Court of Appeals for the Federal Circuit) shall have jurisdiction of appeals from all final decisions of the district courts of the United States, the United States District Court for the District of the Canal Zone, the District Court of Guam, and the District Court of the Virgin Islands, except where a direct review may be had in the Supreme Court. The jurisdiction of the United States Court of Appeals for the Federal Circuit shall be limited to the jurisdiction described in sections 1292(c) and (d) and 1295 of this title.

- **35 U.S.C. § 102.**

§ 102. Conditions for patentability; novelty and loss of right to patent

A person shall be entitled to a patent unless--

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States, or

(c) he has abandoned the invention, or

(d) the invention was first patented or caused to be patented, or was the subject of an inventor's certificate, by the applicant or his legal representatives or assigns in a foreign country prior to the date of the application for patent in this country on an application for patent or inventor's certificate filed more than twelve months before the filing of the application in the United States, or

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an interna-

tional application filed under the treaty defined in section 351(a) shall have the effects for the purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language; [FN1] or

(f) he did not himself invent the subject matter sought to be patented, or

(g)(1) during the course of an interference conducted under section 135 or section 291, another inventor involved therein establishes, to the extent permitted in section 104, that before such person's invention thereof the invention was made by such other inventor and not abandoned, suppressed, or concealed, or (2) before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it. In determining priority of invention under this subsection, there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

[FN1] So in original. The semicolon probably should be a comma.

- **Bayh Dole Act, 35 U.S.C. §§ 200-212 (2009).**

§ 200. Policy and objective

It is the policy and objective of the Congress to use the patent system to promote the utilization of inventions arising from federally supported research or development; to encourage maximum participation of small business firms in federally supported research and development efforts; to promote collaboration between commercial concerns and nonprofit organizations, including universities; to ensure that inventions made by nonprofit organizations and small business firms are used in a manner to promote free competition and enterprise without unduly encumbering future research and discovery; to promote the commercialization and public availability of inventions made in the United States by United States industry and labor; to ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions; and to minimize the costs of administering policies in this area.

§ 207. Domestic and foreign protection of federally owned inventions

(a) Each Federal agency is authorized to--

(1) apply for, obtain, and maintain patents or other forms of protection in the United States and in foreign countries on inventions in which the Federal Government owns a right, title, or interest;

(2) grant nonexclusive, exclusive, or partially exclusive licenses under federally owned inventions, royalty-free or for royalties or other consideration, and on such terms and conditions, including the grant to the licensee of the right of enforcement pursuant to the provisions of chapter 29 of this title as determined appropriate in the public interest;

(3) undertake all other suitable and necessary steps to protect and administer rights to federally owned inventions on behalf of the Federal Government either directly or through contract, including acquiring rights for and administering
royalties to the Federal Government in any invention, but only to the extent the party from whom the rights are acquired voluntarily enters into the transaction, to facilitate the licensing of a federally owned invention; and

(4) transfer custody and administration, in whole or in part, to another Federal agency, of the right, title, or interest in any federally owned invention.

(b) For the purpose of assuring the effective management of Government-owned inventions, the Secretary of Commerce is authorized to--

(1) assist Federal agency efforts to promote the licensing and utilization of Government-owned inventions;

(2) assist Federal agencies in seeking protection and maintaining inventions in foreign countries, including the payment of fees and costs connected therewith; and

(3) consult with and advise Federal agencies as to areas of science and technology research and development with potential for commercial utilization.

- **Title VII of the Civil Rights Act of 1964, 42 U.S.C. §§ 2000e et seq. (2009).**

§ 2000e-3. Other unlawful employment practices

(a) Discrimination for making charges, testifying, assisting, or participating in enforcement proceedings

It shall be an unlawful employment practice for an employer to discriminate against any of his employees or applicants for employment, for an employment agency, or joint labor-management committee controlling apprenticeship or other training or retraining, including on-the-job training programs, to discriminate against any individual, or for a labor organization to discriminate against any member thereof or applicant for membership, because he has opposed any practice made an unlawful employment practice by this subchapter, or because he has made a charge, testified, assisted, or participated in any manner in an investigation, proceeding, or hearing under this subchapter.

(b) Printing or publication of notices or advertisements indicating prohibited preference, limitation, specification, or discrimination; occupational qualification exception

It shall be an unlawful employment practice for an employer, labor organization, employment agency, or joint labor-management committee controlling apprenticeship or other training or retraining, including on-the-job training programs, to print or publish or cause to be printed or published any no-

tice or advertisement relating to employment by such an employer or membership in or any classification or referral for employment by such a labor organization, or relating to any classification or referral for employment by such an employment agency, or relating to admission to, or employment in, any program established to provide apprenticeship or other training by such a joint labor-management committee, indicating any preference, limitation, specification, or discrimination, based on race, color, religion, sex, or national origin, except that such a notice or advertisement may indicate a preference, limitation, specification, or discrimination based on religion, sex, or national origin when religion, sex, or national origin is a bona fide occupational qualification for employment.

§ 2000e-16. Employment by Federal Government

(a) Discriminatory practices prohibited; employees or applicants for employment subject to coverage

All personnel actions affecting employees or applicants for employment (except with regard to aliens employed outside the limits of the United States) in military departments as defined in section 102 of Title 5, in executive agencies as defined in section 105 of Title 5 (including employees and applicants for employment who are paid from nonappropriated funds), in the United States Postal Service and the Postal Regulatory Commission, in those units of the Government of the District of Columbia having positions in the competitive service, and in those units of the judicial branch of the Federal Government having positions in the competitive service, in

the Smithsonian Institution, and in the Government Printing Office, the Government Accountability Office, and the Library of Congress shall be made free from any discrimination based on race, color, religion, sex, or national origin.

(b) Equal Employment Opportunity Commission; enforcement powers; issuance of rules, regulations, etc.; annual review and approval of national and regional equal employment opportunity plans; review and evaluation of equal employment opportunity programs and publication of progress reports; consultations with interested parties; compliance with rules, regulations, etc.; contents of national and regional equal employment opportunity plans; authority of Librarian of Congress

Except as otherwise provided in this subsection, the Equal Employment Opportunity Commission shall have authority to enforce the provisions of subsection (a) of this section through appropriate remedies, including reinstatement or hiring of employees with or without back pay, as will effectuate the policies of this section, and shall issue such rules, regulations, orders and instructions as it deems necessary and appropriate to carry out its responsibilities under this section. The Equal Employment Opportunity Commission shall--

(1) be responsible for the annual review and approval of a national and regional equal employment opportunity plan which each department and agency and each appropriate unit referred to in subsection (a) of this section shall submit in order to maintain an affirmative program of equal

employment opportunity for all such employees and applicants for employment;

(2) be responsible for the review and evaluation of the operation of all agency equal employment opportunity programs, periodically obtaining and publishing (on at least a semiannual basis) progress reports from each such department, agency, or unit; and

(3) consult with and solicit the recommendations of interested individuals, groups, and organizations relating to equal employment opportunity.

The head of each such department, agency, or unit shall comply with such rules, regulations, orders, and instructions which shall include a provision that an employee or applicant for employment shall be notified of any final action taken on any complaint of discrimination filed by him thereunder. The plan submitted by each department, agency, and unit shall include, but not be limited to--

(1) provision for the establishment of training and education programs designed to provide a maximum opportunity for employees to advance so as to perform at their highest potential; and

(2) a description of the qualifications in terms of training and experience relating to equal employment opportunity for the principal and operating officials of each such department, agency, or unit responsible for carrying out the equal employment opportunity program and of the allocation of personnel and resources proposed by such

department, agency, or unit to carry out its equal employment opportunity program.

With respect to employment in the Library of Congress, authorities granted in this subsection to the Equal Employment Opportunity Commission shall be exercised by the Librarian of Congress.

(c) Civil action by employee or applicant for employment for redress of grievances; time for bringing of action; head of department, agency, or unit as defendant

Within 90 days of receipt of notice of final action taken by a department, agency, or unit referred to in subsection (a) of this section, or by the Equal Employment Opportunity Commission upon an appeal from a decision or order of such department, agency, or unit on a complaint of discrimination based on race, color, religion, sex or national origin, brought pursuant to subsection (a) of this section, Executive Order 11478 or any succeeding Executive orders, or after one hundred and eighty days from the filing of the initial charge with the department, agency, or unit or with the Equal Employment Opportunity Commission on appeal from a decision or order of such department, agency, or unit until such time as final action may be taken by a department, agency, or unit, an employee or applicant for employment, if aggrieved by the final disposition of his complaint, or by the failure to take final action on his complaint, may file a civil action as provided in section 2000e-5 of this title, in which civil action the head of the department, agency, or unit, as appropriate, shall be the defendant.

(d) Section 2000e-5(f) through (k) of this title applicable to civil actions

The provisions of section 2000e-5(f) through (k) of this title, as applicable, shall govern civil actions brought hereunder, and the same interest to compensate for delay in payment shall be available as in cases involving nonpublic parties.. [FN1]

(e) Government agency or official not relieved of responsibility to assure nondiscrimination in employment or equal employment opportunity

Nothing contained in this Act shall relieve any Government agency or official of its or his primary responsibility to assure nondiscrimination in employment as required by the Constitution and statutes or of its or his responsibilities under Executive Order 11478 relating to equal employment opportunity in the Federal Government.

(f) Section 2000e-5(e)(3) of this title shall apply to complaints of discrimination in compensation under this section.

§ 2000e-16a. Short title; purpose; definition

(a) Short title

Sections 2000e-16a to 2000e-16c of this title may be cited as the "Government Employee Rights Act of 1991".

(b) Purpose

The purpose of sections 2000e-16a to 2000e-16c of this title is to provide procedures to protect the rights of certain government employees, with respect to their public employment, to be free of discrimination on the basis of race, color, religion, sex, national origin, age, or disability.

(c) "Violation" defined

For purposes of sections 2000e-16a to 2000e-16c of this title, the term "violation" means a practice that violates section 2000e-16b(a) of this title.

§ 2000e-16b. Discriminatory practices prohibited

(a) Practices

All personnel actions affecting the Presidential appointees described in section 1219 of Title 2 or the State employees described in section 2000e-16c of this title shall be made free from any discrimination based on--

(1) race, color, religion, sex, or national origin, within the meaning of section 2000e-16 of this title;

(2) age, within the meaning of section 633a of Title 29; or

(3) disability, within the meaning of section 791 of Title 29 and sections 12112 to 12114 of this title.

(b) Remedies

The remedies referred to in sections 1219(a)(1) of Title 2 and 2000e-16c(a) of this title--

(1) may include, in the case of a determination that a violation of subsection (a)(1) or (a)(3) of this section has occurred, such remedies as would be appropriate if awarded under sections 2000e-5(g), 2000e-5(k), and 2000e-16(d) of this title, and such compensatory damages as would be appropriate if awarded under section 1981 or sections 1981a(a) and 1981a(b)(2) of this title;

(2) may include, in the case of a determination that a violation of subsection (a)(2) of this section has occurred, such remedies as would be appropriate if awarded under section 633a(c) of Title 29; and

(3) may not include punitive damages.

- **Federal Rule of Civil Procedure 37.**

Rule 37. Failure to Make Disclosures or to Cooperate in Discovery; Sanctions

(a) Motion for an Order Compelling Disclosure or Discovery.

(1) ***In General.*** On notice to other parties and all affected persons, a party may move for an order compelling disclosure or discovery. The motion must include a certification that the movant has in good faith conferred or attempted to confer

with the person or party failing to make disclosure or discovery in an effort to obtain it without court action.

(2) ***Appropriate Court.*** A motion for an order to a party must be made in the court where the action is pending. A motion for an order to a nonparty must be made in the court where the discovery is or will be taken.

(3) ***Specific Motions.***

(B) *To Compel a Discovery Response.* A party seeking discovery may move for an order compelling an answer, designation, production, or inspection. This motion may be made if:

(i) a deponent fails to answer a question asked under Rule 30 or 31;

(C) *Related to a Deposition.* When taking an oral deposition, the party asking a question may complete or adjourn the examination before moving for an order.

(4) ***Evasive or Incomplete Disclosure, Answer, or Response.*** For purposes of this subdivision (a), an evasive or incomplete disclosure, answer, or response must be treated as a failure to disclose, answer, or respond.

(5) ***Payment of Expenses; Protective Orders.***

(A) *If the Motion Is Granted (or Disclosure or Discovery Is Provided After Filing).* If the motion

is granted--or if the disclosure or requested discovery is provided after the motion was filed--the court must, after giving an opportunity to be heard, require the party or deponent whose conduct necessitated the motion, the party or attorney advising that conduct, or both to pay the movant's reasonable expenses incurred in making the motion, including attorney's fees. But the court must not order this payment if:

(i) the movant filed the motion before attempting in good faith to obtain the disclosure or discovery without court action;

(ii) the opposing party's nondisclosure, response, or objection was substantially justified; or

(iii) other circumstances make an award of expenses unjust.

(B) *If the Motion Is Denied.* If the motion is denied, the court may issue any protective order authorized under Rule 26(c) and must, after giving an opportunity to be heard, require the movant, the attorney filing the motion, or both to pay the party or deponent who opposed the motion its reasonable expenses incurred in opposing the motion, including attorney's fees. But the court must not order this payment if the motion was substantially justified or other circumstances make an award of expenses unjust.

(C) *If the Motion Is Granted in Part and Denied in Part.*If the motion is granted in part and denied in part, the court may issue any protective

order authorized under Rule 26(c) and may, after giving an opportunity to be heard, apportion the reasonable expenses for the motion.

(b) Failure to Comply with a Court Order.

(1) ***Sanctions in the District Where the Deposition Is Taken.*** If the court where the discovery is taken orders a deponent to be sworn or to answer a question and the deponent fails to obey, the failure may be treated as contempt of court.

(2) ***Sanctions in the District Where the Action Is Pending.***

(A) *For Not Obeying a Discovery Order.* If a party or a party's officer, director, or managing agent--or a witness designated under Rule 30(b)(6) or 31(a)(4)--fails to obey an order to provide or permit discovery, including an order under Rule 26(f), 35, or 37(a), the court where the action is pending may issue further just orders. They may include the following:

(i) directing that the matters embraced in the order or other designated facts be taken as established for purposes of the action, as the prevailing party claims;

(ii) prohibiting the disobedient party from supporting or opposing designated claims or defenses, or from introducing designated matters in evidence;

(iii) striking pleadings in whole or in part;

(iv) staying further proceedings until the order is obeyed;

(v) dismissing the action or proceeding in whole or in part;

(vi) rendering a default judgment against the disobedient party; or

(vii) treating as contempt of court the failure to obey any order except an order to submit to a physical or mental examination.

(B) *For Not Producing a Person for Examination.* If a party fails to comply with an order under Rule 35(a) requiring it to produce another person for examination, the court may issue any of the orders listed in Rule 37(b)(2)(A)(i)-(vi), unless the disobedient party shows that it cannot produce the other person.

(C) *Payment of Expenses.* Instead of or in addition to the orders above, the court must order the disobedient party, the attorney advising that party, or both to pay the reasonable expenses, including attorney's fees, caused by the failure, unless the failure was substantially justified or other circumstances make an award of expenses unjust.

(c) Failure to Disclose, to Supplement an Earlier Response, or to Admit.

(2) ***Failure to Admit.*** If a party fails to admit what is requested under Rule 36 and if the requesting party later proves a document to be ge-

nuine or the matter true, the requesting party may move that the party who failed to admit pay the reasonable expenses, including attorney's fees, incurred in making that proof. The court must so order unless:

(A) the request was held objectionable under Rule 36(a);

(B) the admission sought was of no substantial importance;

(C) the party failing to admit had a reasonable ground to believe that it might prevail on the matter; or

(D) there was other good reason for the failure to admit.

APPENDIX D

For Opinion See: 2007 WL 1774376 2008 WL 2761246 2008 WL 4372641

Court:	U.S. DISTRICT COURT EASTERN DISTRICT OF MICHIGAN (DETROIT)
Case Title:	BROWN ET AL v. VETERANS AFFAIRS, DEPARTMENT OF
Case:	2:04-CV-73411
Judge:	DISTRICT JUDGE JOHN CORBETT O'MEARA
Date Filed:	09/02/2004
Date Closed/ Terminated:	07/15/2008 [Appeal filed, 12/08/2009]
Other Dockets:	UNITED STATES COURT OF APPEALS, 05-01673 UNITED STATES COURT OF APPEALS-SIXTH CIRCUIT 08-02506

CASE INFORMATION

Case Number:	2:04CV7341
Referred To:	MAGISTRATE JUDGE R. STEVEN WHALEN
Jury Demand:	NONE
Demand:	$125,000,000,000.00
Nature of Suit:	TORTS: OTHER PERSONAL INJURY (360)
Key Nature of Suit:	TORTS/NEGLIGENCE; PERSONAL INJURY; OTHER FEDERAL ACTIONS (430.75.25)

Table petitioner wrote and mailed to the Honorable Senators Barbara Mikulski and Paul Sarbanes; and the Assistant Inspector General, LTC Ulysses Miranda, Medical Research and Materiel Command (MRMC), Fort Detrick, on or about June 16, 2003, copied from Exhibit 10 [numbered pages 7-8], Dist. Ct. Dkt. 25:

Table. Symptom-by-symptom comparison of the major symptoms of "Gulf War Syndrome" [GWS] recapitulated in chronically *Leishmania* infected foxhounds.

Chronic Leishmania-Infected Foxhounds	Human Gulf War Syndrome
1. Transient Behavior Abnormality • Atypical transient Shyness • Atypical transient Aggression • Micro-seizures due to micro-stroke events, TIAs (transient ischemic attacks) in the	1. Transient behavior abnormality typically explained as post-traumatic stress disorder. Memory loss-characteristically attributed to post-traumatic stress disorder.

dura matter and choroid plexus could result in transient paralysis (paresis) in limbs-frequently manifest after vigorous exercise.	Similar paresis has been reported for Gulf War Syndrome patients with No medical explanation offered.

See dura mater and choroid plexus powerpoint figures attached. Compare with Leiby, *Washington Post* 30 Dec 2002 [Style Section C, pages 1-2], photo [in original, Exhibit not here] attached [showing brain scan of Gulf War patient with apparent sponge-like holes], page 10. *Leishmania infantum* were isolated from the dura mater and choroids plexus of chronically infected [in nature] dogs (as previously reported also by Garcia-Alonso, et al[.], 1996; Nieto, et al., 1996; Vinuelas, et al., 2001) with pathology [of the brain, described as spongiform encephalopathy] shown/described in the Leiby news article.

2. Chronic fatigue-hypoadrenalism [adrenal insufficiency]due to leishmanial-induced adrenal pathology (Addison's	2. Chronic fatigue syndrome, again most often explained as post-traumatic stress syndrome.

Disease-like symptoms) includes nonresponsiveness to ACTH (test) stimulation; with possible Na^+/K^+ [sodium/potassium] imbalance leading to intermittent heart arythmia with fatigue.	Heart symptoms most often explained as random case events unrelated to Gulf War.

Note: Autoimmune neurologic diseases (e.g. amylotropic lateral sclerosis, ALS, Nicolson et al., 2002) [for leishmaniases] are explained from leakage/vascular permeability of the blood-brain-barrier to leishmanial infectious neurologic cellular debris because of adrenal-cortical malfunction hypoadrenalism[.] (Long and Holaday, 1985)

3. Increased susceptibility/incidence of neoplasia of all tissue types. This is due to cell mediated immunodepression known to accompany chronic visceral	3. Increased incidence of cancer or neoplasia explained based on chemical exposures/ fires/spent uranium used in weapons.

leishmaniasis infection.	
4. Transmission between male-to-female (and vice versa) breeding dogs and to resultant puppies. Causes increased Miscarriage, difficult whelping-stillbirths, difficulty supporting nursing, and puppies born healthy but which show leishmanial symptoms of infection typically between one-two years of age.	4. Transmission between husbands and wives of Gulf War veterans and to their children conceived after the Middle East exposure: some with Gulf War Syndrome symptoms, some with attention deficient disorders (see #1 on left), cancers (#3 on left), stillbirth/miscarriage (#4 on left) at higher rate [than comparable populations].
5. Arthritis, joint swelling[,] musculoskeletal pain.	5. Musculoskeletal pain, arthritis-like symptoms.
6. Ocular bilateral keratoconjunctivitis	6. Ocular/eye symptoms.

and/or uveitis (inflammation of the iris, ciliary body, and choroid) often with ocular oedema/swelling and glaucoma.

Photo showing published canine and human ocular pathology is attached ([in original from] Ferrer, 1999;[and] Napier, 1946, respectively). *See also*[,] the dura matter is contiguous with the eye, photo attached [in original]. (emphasis added)

7. New oral drug already FDA-approved [for other indications] to lower cholesterol, acts to block intracellular nutrients to leishmanial parasites, thereby starving them. This drug has negligible toxicity and [is] orally administered. [New ICBG Grant Research	7. Current anti-leishmanials are too toxic for prophylactic [preventative] use, leishmanial drug resistance is widespread throughout endemic regions worldwide, too toxic to administer except to proven leishmanial infected patients.

Drugs on which
petitioner is author
and the patent's
lead inventor,
Question
Presented II.]

The web page (www.gulfwar.org/Gulf_War/eval.html, 1995) summarized similar findings as a percentage of 1,000 active-duty, reserve and retired gulf war veterans who are experiencing health problems and completed medical evaluation. The diagnoses include: psychological, 26%; musculoskeletal, 16%, gastrointestinal, 7%; respiratory, 6%; nervous system, 6%; skin and subcutaneous, 5%; infectious disease, 4%; endocrine, 3%; genitourinary, 2%; neoplasm, 1%; 15% could not be diagnosed (includes such symptoms as headaches and memory loss, fatigue, sleep disorders and musculoskeletal complaints); and 9% were healthy. The website further notes: "Some veterans have reported their offspring have birth defects or their spouses have health problems which they attribute to the veteran's Persian Gulf service."

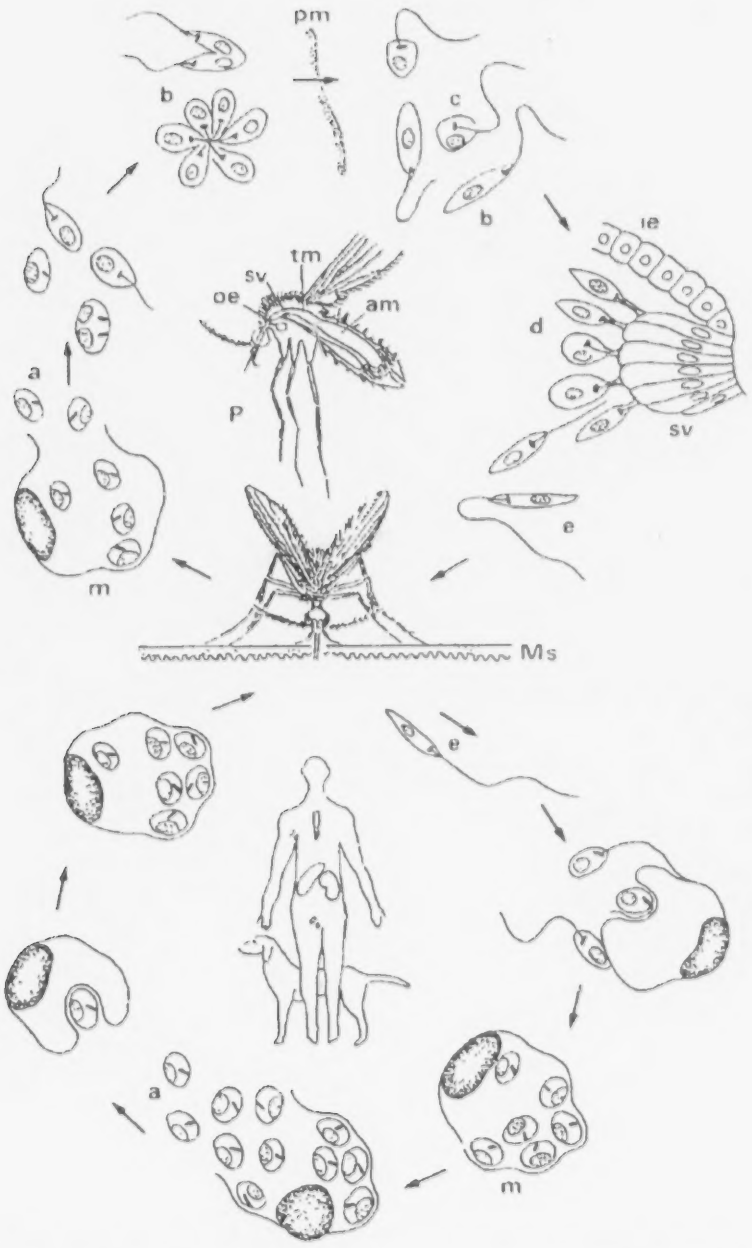

Figure 75.1: Life cycle of the *Leishmania* parasites. P: phlebotomine sandfly, pm: pentrophic membrane, am: abdominal midgut; tm thoracic midgut, oe. oesophagus; sv. stomodeal valve; ie: intestinal epithelium, Ms mammal skin ; m: macrophage. a. amastigotes; b: nectomonad promastigotes; c: paramastigotes; d: attached haptomonads, e: metacyclic promastigotes. (Original drawing by D M Jarry.)

Chapter 75, Leishmaniasis, J.P. Dedet and F. Pratlong, pages 1342, 1343, and 1344.
Manson's Tropical Diseases, Twenty-first Edition, 2003.

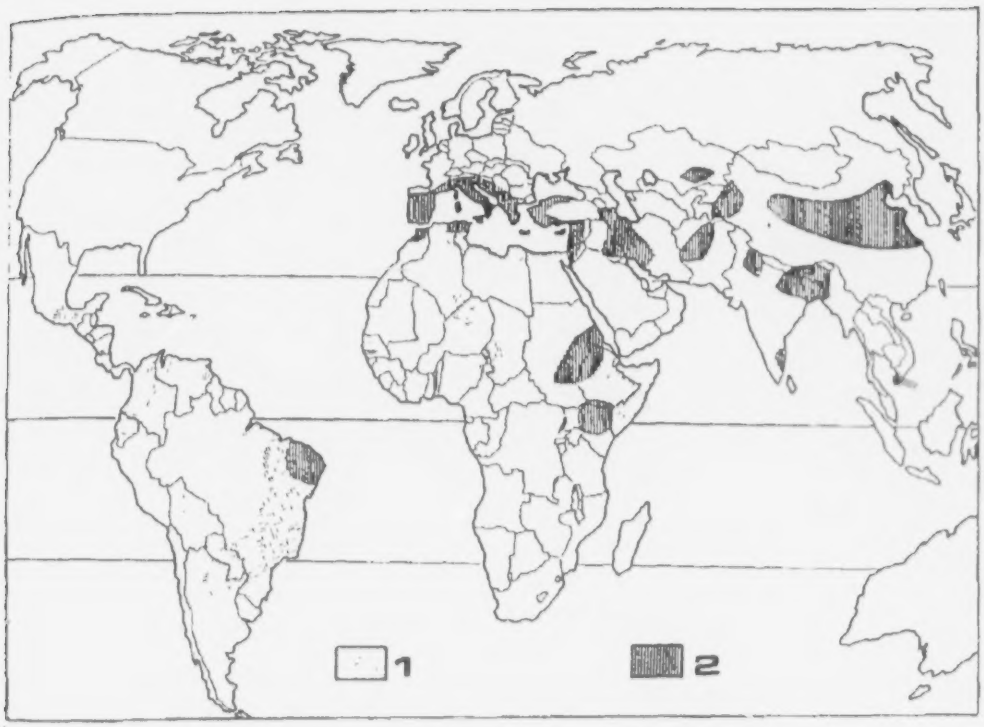

Figure 75.2: Geographical distribution of visceral leishmaniasis 1: Low-endemicity areas 2: High-endemicity areas

Chapter 75, Leishmaniasis, J.P. Dedet and F. Pratlong,
pages 1342, 1343, and 1344.
Manson's Tropical Diseases, Twenty-first Edition, 2003.

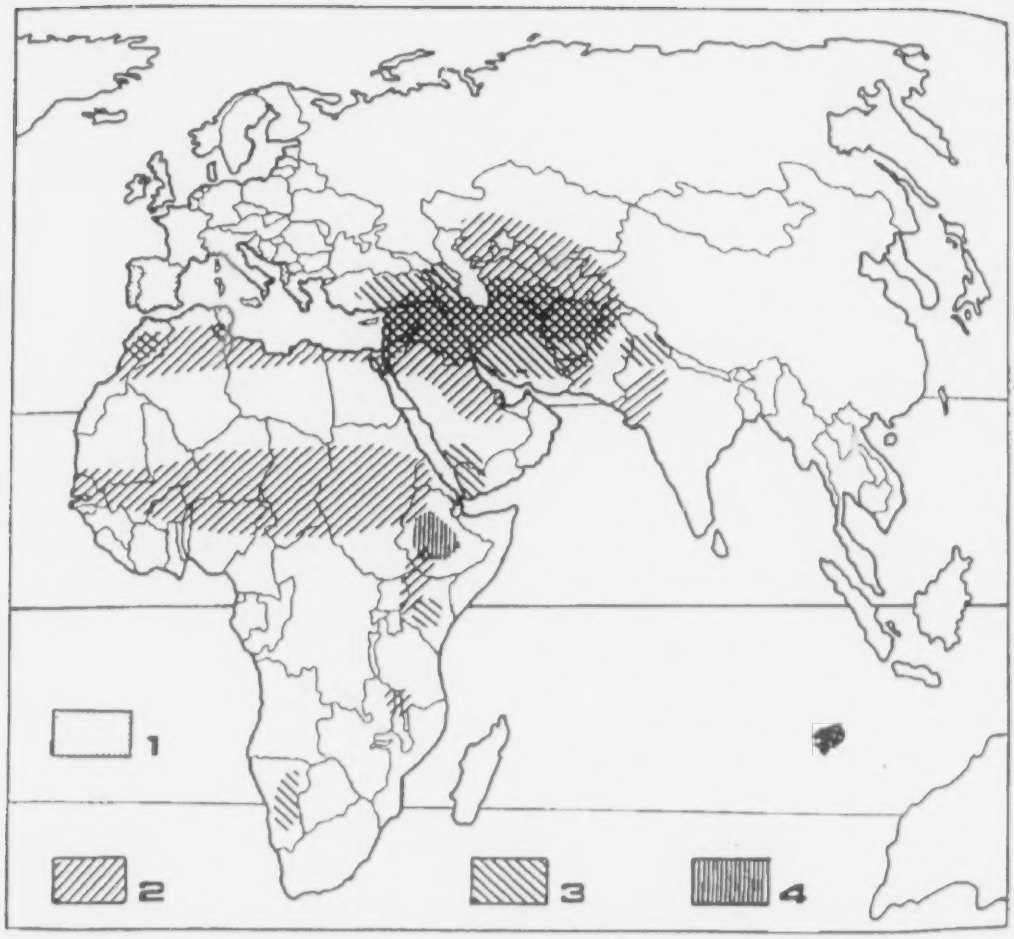

Figure 75.3: Geographical distribution of Old World CL. 1. *L. infantum* CL. 2. Zoonotic CL caused by *L. major*. 3. *L. tropica* CL. 4. *L. aethiopica* CL.

Chapter 75, Leishmaniasis, J.P. Dedet and F. Pratlong,
pages 1342, 1343, and 1344.
Manson's Tropical Diseases, Twenty-first Edition, 2003.

APPENDIX E

REPRESENTATIVE ABSTRACTS OF PRESENTATIONS APPROVED BY THE SCIENTIFIC SOCIETY BY PEER-REVIEW BUT DENIED APPROVAL, UNDER WRITTEN THREAT OF LEGAL PROSECUTION OF PETITIONER BY WRAIR. CDC PRESENTED THE FIRST ABSTRACT ABSENT WRAIR'S PRIOR APPROVAL, GIVEN RETROSPECTIVELY.

EMERGENCE OF CANINE VISCERAL LEISHMANIASIS IN NORTH AMERICA, 2000-2003.

Schantz PM, Steurer F, Duprey Z, Rooney J, Kirchhoff LV, L Rowton E, Jackson J, Gramiccia M. Division of Parasitic Diseases, National Center For Infectious Diseases, Centers For Disease Control and Prevention, Atlanta, GA ; Univ. Iowa, Iowa City IA; Walter Reed Army Institute of Research, Wash. D.C. and Istit. Superiore di Sanita., Rome, Italy.

Visceral leishmaniasis (VL) is a vector borne infection of global importance caused by protozoa of the genus *Leishmania* that infect humans, dogs, and other mammals. VL is endemic in many countries of the world and, until recently, was thought to be an imported disease in North America. Beginning in the late summer of 1999, this infection was identified as the agent causing high morbidity and mortality among Foxhounds in a kennel in New York State. An investigation was initiated to determine the geographic extent, prevalence and modes of

transmission of leishmaniasis in Foxhounds, other canids and associated humans in North America. Serologic testing of over 12,000 foxhounds, other breeds of dogs, and wild canids in 34 states and 4 Canadian provinces was performed; several rounds of testing were offered during three years. *Leishmania* infections detected by serodiagnosis were confirmed whenever possible by culture of the organism. Foxhounds infected with *L. infantum* were identified in 18 states and 2 Canadian Provinces. Possible zoonotic infection of humans associated with infected dogs was assessed by voluntary serologic testing of persons associated with these animals. No clinical or serologic evidence of infection was found in humans associated with infected Foxhounds or in other breeds of dogs and wild canids. *Transmission appears to occur directly from dog to dog, including from pregnant dam to pups, and via blood transfusion. Trypanosoma cruzi*, another potentially zoonotic agent of infection, was also detected in Foxhounds in many states and, because of serologic cross-reactivity, it was necessary to use specific serologic assays to distinguish infections by these two agents. L. infantum MON1, *the agent of visceral leishmaniasis in humans and dogs*, is established and widely distributed in Foxhounds but not in other breeds of dogs or humans in North America. Transmission of the protozoal agent in North America appears limited to direct dog-to-dog mechanisms, however, if the organism becomes adapted for vector transmission by indigenous phlebotomines, the possibility of exposure of humans will be greatly increased. (emphasis added)

Submitted and accepted for presentation at the 53rd Annual Meeting of the American Society of

Tropical Medicine and Hygiene (ASTMH), 7-11 November 2004, Fontainebleau Hilton, Miami Beach, Florida, USA.

Published in *American Journal of Tropical Medicine and Hygiene* (2004) 71(4):44.

CHRONIC VISCERAL LEISHMANIASIS (VL): CELL RECEPTORS AND NEUROLOGIC PATHOLOGY.

Jackson, JE; Iwu MM; Okunji CO; Van Gessel Y; Schantz P; Steurer F; Kollmar E; Topper M; Gramiccia M. Divisions of Experimental Therapeutics and Pathology, Walter Reed Army Institute of Research, Silver Spring, MD; Bioresources Development and Conservation Programme, Silver Spring, MD; Division of Parasitic Diseases, NCID, Centers for Disease Control and Prevention (CDC), Atlanta, GA; Village Animal Hospital, Millbrook, NY; Laboratorio di Parassitologia, Istituto Superiore di Sanita, Rome, Italy.

Chronic leishmaniases have not typically been considered infections having potential neurologic pathology. However, recent and historic, molecular and pathologic reports include: (1) |Leishmania mexicana amazonensis| (|Lma|) synthesize an intracellular adhesion molecule, ICAM-L, having sequence homology with human ICAM-5 (telencephalin, brain unique cell surface protein). ICAM-L facilitates entry into host cells. (2) ICAMs may bind both via homophilic and heterphilic interaction. (3) Human ICAM-5 appears around birth and persists in adult animals/humans. (4) The

CAMs are known to be critical to many inter- and intra- signalling including: the initial axonal growth and guidance; target selection; synapse stabilization and plasticity; myelination and nerve regeneration after injury. (5) Leucocyte adhesion to purified ICAM-5 is temperature dependent, requires Mg\++/ or Mn\++/ and binding is increased by leucocyte stimulation. (6) In 1923 it was reported that VL "is essentially a disease of one tissue of the body. This tissue is the endothelium..." (7) Monocyte recruitment into early lesions depends on endothelial adhesiveness for monocytes and lymphocytes. Our investigative team confirmed prior investigations (>10 published 1925-present) of chronic, natural VL infection in nerve tissues of foxhounds and their progeny. Neurologic symptoms (e.g. behavior: unusual aggression/shyness; seizures; paresis; ocular lesions, etc.) frequently precede both CDC IFA detection threshold and classic VL symptoms. Previously reported VL neurologic pathogenesis includes features typical of other infectious neuropathies: e.g. blood-brain-barrier hyperpermeability, sponge-like reaction accompanied by neuronal degeneration, mobilization of glial cells with accumulation of amyloid deposits, mononuclear keratoconjunctivitis, decreased number of neurons in the hippocampus, diffuse chromatolysis and active neuronophagia in the cerebral cortex. We identified 4 additional cell receptors possibly implicated in leishmanial neurologic pathology. Novel antileishmanial drugs known to inhibit these 4 receptors' functions reduced parasitemia below detection, ameliorating symptoms in two dogs. Possible pathologic and therapeutic implications of these data will be presented.

Submitted and accepted for presentation at the 52nd (Bicentennial) Annual Meeting of the American Society of Tropical Medicine and Hygiene (ASTMH), 3-7 December 2003, Philadelphia Downtown Marriott, Philadelphia, Pennsylvania, USA.

Published in *American Journal of Tropical Medicine and Hygiene* (2003) 69(3):402.

CHRONIC CANINE VISCERAL LEISHMANIASIS (VL): PREPATENT VL NEUROLOGIC MANIFESTATIONS.

Jackson, JE; Iwu MM; Okunji CO; Van Gessel Y; Schantz P; Steurer F; Topper M; Gramiccia M. Divisions of Experimental Therapeutics and Pathology, Walter Reed Army Institute of Research, Silver Spring, MD; Bioresources Development and Conservation Programme, Silver Spring, MD; Division of Parasitic Diseases, NCID, Centers for Disease Control and Prevention (CDC), Atlanta, GA; Laboratorio di Parassitologia, Instituto Superiore di Sanita, Rome, Italy.

Visceral leishmaniasis is known to localize in liver, spleen, bone marrow and lymph nodes. However, at the turn of the century British pathologists in India studying "dum-dum fever" victims reported in chronic VL amastigotes also localized in brain "meninges." In Northern Africa, paralytic symptoms (foot drop) were reported associated with VL and disappeared following pentavalent antimony therapy. Our group investigated a widespread outbreak of canine leishmaniasis across 21 states of the USA and 2 Canadian provinces. The etiologic agent has

been identified as Leishmania (Leishmania) infantum MON1 (Li). This investigation showed canine vertical VL transmission is common in North America. In Germany, human vertical VL transmission has been verified in children born of asymptomatic refugees from VL endemic regions. Recapitulating findings of the early pathologists, we isolated Li in culture from sex organs (males and females), adrenal, dura mater, and choroid plexus from chronic leishmanial infections in dogs, presumptively infected from birth. Frequently, such animals lacked typical leishmanial symptoms (wasting, skin lesions, alopecia, ocular lesions, kidney failure, anemia, epistaxis, arthritic-like swelling joints of limbs), i.e. such symptoms were inapparent, transient (appeared and disappeared without specific treatment), or absent. However, these dogs had positive CDC IFA titers, -histopathology, and/or -biopsy culture for Li infection. Case histories will be presented illustrating chronically VL infected dogs for which initial leishmanial symptoms included only: a) changes in typical behavior, e.g. transient aggression (exercise associated); b) photophobia; c) head sensitivity (aversion to gentle touch); d) brain disfunctions, including paralytic episodes or seizures, noted as "exercise intolerance." In many, it was only at necropsy that Li infection was verified. These cases confounded proper clinical diagnosis because the pathologic manifestations were considered outside the differential for leishmanial infection. Other clinical explanations for these symptoms were excluded based on full necropsy histopathologic findings compatible with leishmanial infection.

Abstract submitted for presentation ASTMH, 10-14 Nov 2002, Denver, Colorado

Published in *American Journal of Tropical Medicine and Hygiene* (2002) 67(2):222-223.

VISCERAL LEISHMANIASIS (VL): EVIDENCE IN DOGS FOR ASSOCIATION WITH CANCERS DUE TO DEPRESSED VL CELLULAR IMMUNITY (CMI).

Jackson, JE; Van Gessell, Y; Schantz P; Steurer, F; Kollmar, E; Gramiccia, M; Scott, P; Breitschwerdt, E; Gaskin, A; Lamothe, J; Topper, M. Divisions of Experimental Therapeutics and Pathology, Walter Reed Army Institute of Research, Silver Spring, MD; Division of Parasitic Diseases, NCID, Centers for Disease Control and Prevention (CDC), Atlanta, GA; Village Animal Hospital, Millbrook, NY; Istituto Superiore di Sanità, Rome, Italy; School of Veterinary Medicine, University of Pennsylvania, Philadelphia, PA; College of Veterinary Medicine, North Carolina State University, Raleigh, NC; Clinique Veterinaire de Carros, Carros, France.

Numerous studies established clinical frequency of VL and CMI depression. However, CMI depression during early asymptomatic infection stages in chronic disease has not been extensively investigated. Asymptomatic human adults and canines infected with Leishmania (Leishmania) infantum are reported to comprise the majority. For several years, our group has been actively investigating a widespread outbreak of endemic canine leishma-

niasis in North America. This investigation included repeated CDC IFA screening of tens of thousands of dogs. In the majority, IFA-positive dogs showed few, if any, overt disease symptoms, at medium to low-range IFA titers, i.e. </=1:128. Data to be presented showed that the leishmanial infection is often vertically transmitted, from parents-to-offspring, in North America. To limit further disease spread/contact, many owners of low-titer IFA-positive dogs' elected either the dogs' euthanasia or donation to scientific institutions for disease investigation. Both CDC and WRAIR have shown that even asymptomatic animals are indeed infected with leishmanial parasites by culture at all IFA titers from 1:16->/=1:512. When such chronic asymptomatic animals' data were correlated from many clinics in the North America and one clinic in a VL endemic region in France, it was evident that there was a much higher cancer rate associated with chronic asymptomatic L. infantum infection than would be anticipated based on the uninfected population of dogs of the same breed. Many cancer:leishmanial hounds in North America were less than 5 years old. Neoplasms were of diverse cellular origin. Leishmanial amastigotes were easily cultured from neoplastic tissue and in some cases leishmanial antigen was detected immunohistochemically within neoplastic cells. Based on these preliminary data, our hypothesis is that even before clinical symptoms are evident, chronically infected dogs experience CMI depression predisposing them to cancer at earlier age and with higher frequency than the parallel non-leishmanial infected population

For presentation at ASTMH, 10-14 Nov 2002 in Denver, Colorado.

Published: American Journal Tropical Medicine and Hygiene (2002) 67(2):223.

NOVEL ORAL THERAPY FOR VISCERAL LEISHMANIASIS (VL): DRUG EFFICACY IN DOGS PROVIDED EVIDENCE FOR A DUAL RECEPTOR BASED MECHANISM-OF-ACTION.

Jackson JE; Iwu MM; Okunji CO; Van Gessel Y; Schantz P; Schuster BG; Steurer F;Topper M; Gramiccia M. Divisions of Experimental Therapeutics and Pathology, Walter Reed Army Institute of Research, Silver Spring, MD; Bioresources Development and Conservation Programme, Silver Spring, MD; Division of Parasitic Diseases, NCID, Centers for Disease Control and Prevention (CDC), Atlanta, GA; Laboratorio di Parassitologia, Instituto Superiore di Sanita, Rome Italy.

Visceral leishmaniasis is known to localize in liver, spleen, bone marrow and lymph nodes. However, at the turn of the century British pathologists in India reported in chronic VL (fatal human cases) amastigotes also populated such diverse tissues as kidney, brain, etc.. Our group has investigated an outbreak of canine leishmaniasis across 21 states of the USA and 2 provinces in Canada. Evidence from this North American investigation is that vertical leishmanial transmission from either the sire or dam to the resultant puppies is common. Repeating work of the British pathologists, we investigated and treated chronic leishmanial infections

in dogs, presumptively infected from birth. In these animals, besides liver, bone marrow, spleen and lymph nodes, amastigotes are routinely isolated from sex organs (males and females), adrenal, and dura mater, using "gold standard" biopsy culture. One factor these diverse tissues share is a high number of low-density lipoprotein (LDL) receptors. *Leishmania* require, but can not synthesize, cholesterol. *Leishmania* do synthesize ergosterol, a sterol shared with fungi, but not, with humans. Our hypothesis was that treating infected dogs with a HMGCo-A reductase inhibitor (FDA-approved to lower cholesterol), would reduce host provided cholesterol as well as block leishmanial ergosterol synthesis, thereby, reducing parasite numbers. In a preliminary trial using naturally *Leishmania (Leishmania) infantum* (Li) infected North American dogs, our hypothesis was supported. Further, we will present evidence that these drugs work better than anticipated to eliminate parasites from chronically infected dogs because the HMGCo-A reductase inhibitor actually inhibits both the LDL- and a second receptor's functions essential to Li parasites' survival within mammalian host cells. It is the inhibition of two receptors' functions which allows this widely used oral antihyperlipidemic drug, Mevacor® (lovastatin), effectively to suppress this viscero-cutaneous leishmanial infection in the dogs. We will also present preliminary data on prophylactic activity of Mevacor® in this canine model.

Abstract submitted for presentation ASTMH, 10-14 Nov 2002, Denver, Colorado

Published in *American Journal of Tropical Medicine and Hygiene* (2002) 67(2):287-288.

APPENDIX F

(i) Twenty (20) Peer-reviewed Science Journal Publications Reporting Leishmanial Infections of the Central Nervous System: Brain (Including the Dura Mater [tough outer membrane of brain] and Choroid Plexus [capillary blood network continuous between brain and retina or eyes], Spinal Column, and Peripheral Nerves of Humans, Monkeys, Dogs and Rodents.

(ii) Three (3) Representative Peer-reviewed Science Journal Publications Reporting 40 Years or More *Leishmania* Infection Asymptomatic Latency.

(i) Abreu-Silva AL, Calabrese KS, Tedesco RC, Mortara RA, Goncalves da Costa SC, 2003. Central nervous system involvement in experimental infection with *Leishmania (Leishmania) amazonensis*. *Am J Trop Med Hyg* 68(6):661-665.

Avtsyn AP, Berezina EK, Kenig EE, Dursunova SM, Belova EM, Shetegelman LA, Zhukov VG, 1971. [Experimental model of leishmaniasis meningoencephalitis.] [Article in Russian.] *Antibiotiki* 16(10):885-888.

Beaver PC, Jung RC, Cupp EW, 1984. Clinical Parasitology, ninth edition, Lea and Febiger, Philadelphia, pp. 55-77.

Carswell J, 1953. Kala-azar at Kitui. *East African Medical Journal* 30:287-293.

Garcia-Alonso M, Nieto CG, Blanco A, Requena JM, Alsonso C, Navarrete I, 1996. Presence of antibodies in the aqueous humor and cerebrospinal fluid during *Leishmania* infections in dogs. Pathologic features at the central nervous system. *Parasite Immunol* 18(11):539-546.

Hashim FA, Ahmed AE, El Hassan M, El Mubarak MH, Yagi H, Ibrahim EN, Ali MS, 1995. Neurologic changes in visceral leishmaniasis. *Am J Trop Med Hyg* 52(2):149-154.

Kubba R, El Hassan AM, Al-Gindan Y, Omer AH, Kutty ML, Saeed MB, 1987. Peripheral nerve involvement in cutaneous leishmaniasis (Old World). *Int J Dermatol* 26(8):527-531.

Meleney HE, 1925. The histopathology of kala-azar in the hamster, monkey and man. *Am J Pathol* 1:147-168.

Foglia Manzillo F, Papacone R, Cappiello S, De Santo R, Bianciardi P, Oliva G. 2009 Resolution of tongue lesions caused by *Leishmania infantum* in a dog treated with the association miltefosine-allopurinol. *Parasit Vectors* 26(2 Suppl) 1:S6.

Garin YJ, Sulahian A, Meneceur P, Pratlong F, Prina E, Gangneux J, Dedet JP, Derouin F. 2001. Experimental pathogenicity of a presumed monoxenous trypanosomatid isolated from humans in a murine model. *J Eukaryot Microbiol* 48(2):170-176.

Melo GD, Marcondes M, Vasconcelos RO, Machado GF. 2009. Leucocyte entry into the CNS of *Leishmania chagasi* naturally infected dogs. *Vet Parasitol* 162(3-4):248-256.

Mustafa D, 1965. Neurologic disturbances in visceral leishmaniasis. *J Trop Med Hyg* 68:248-250.

Nicolau S, Perard CH, 1936. Etude histo-physiopathologique de l'oeil et du systeme nerveux dans la leishmaniose generalisee du chien. *Ann Inst Pasteur* 57(5):463-486.

Nieto CG, Vinuelas J, Blanco A, Garcia-Alonso M, Verdugo SG, Navarrete I. 1996. Detection of *Leishmania infantum* amastigotes in the canine choroid plexus. *Vet Rec* 139(14):346-347.

Prasad LSN, Sen S, 1996. Migration of *Leishmania donovani* amastigotes in the cerebrospinal fluid. *Am J Trop Med Hyg* 55(6):652-654.

Satti MB, El Hassan AM, Al-Gindan Y, Osman MA, Al-Sohaibani MO, 1989. Peripheral neural involvement in cutaneous leishmaniasis: a pathological study of human and experimental animal lesions. *Int J Dermatol* 28(4):243-247.

Shortt HE, 1923. The pathology of acute experimental kala-azar in monkeys. *Indian J Med Research* 11:186-195.

Tafuri WL, Santos RL, Arantes RM, Concalves R, de Melo MN, Michalick MS, Tafuri WL.

2004. An alternative immunochemical method for detecting *Leishmania* amastigotes in paraffin-embedded canine tissues. *J Immunol Methods* 292(1-2):17-23.

Thorson RE, Bailey WS, Hoerlein BF, Seibold HR, 1955. A case of imported visceral leishmaniasis of a dog in the United States. *Am J Trop Med Hyg* 4:18-22.

Vinuelas J, Garcia-Alonso M, Ferrando L, Navarrete I, Molano I, Miron C, Carcelen J, Alonso C, Nieto CG, 2001. Meningeal leishmaniosis induced by *Leishmania infantum* in naturally infected dogs. *Vet Parasitol* 101(1):23-27.

(ii) Czechowicz RT, Millard TP, Smith HR, Ashton RE, Lucas SS, Hay RJ, 1999. Reactivation of cutaneous leishmaniasis after surgery. *Br J Dermatol* 141(6):1113-1116. ["We describe an 85 year old man who developed CL on his face after recent cutaneous surgery in that site. This case is also unusual because the most likely source of exposure to the infection occurred over 50 years previously."]

Guilland V, Hill MP, Piens MA, Barrut D, Moullin G, 1991. [Cutaneous leishmaniasis with 48 years development.] [Article in French] *Ann Dermatol Venereol* 118(11):850-851.

Jewell AP, Giles FJ, 1996. Cutaneous manifestation of leishmaniasis 40 years after exposure in a patient with chronic lymphocytic leukaemia. *Leuk Lymphoma* 21(3-4):347-349.

APPENDIX G

Thirty-seven (37) Peer-reviewed Science Journal Publications Reporting Leishmanial Congenital Transmission (Parent-to-Offspring) and Sexual/Genital Infection in Humans/Dogs.

[Note: Kala azar, or black fever, is visceral leishmaniasis.]

Sexual/Genital Infection:

Castro Coto A, Hidalgo Hidalgo H, Solano Aguilar E, Coto Chacon F, 1987. [Leishmaniasis of the genital organs.][Article in Spanish] *Med Cut Ibero Lat Am* 15(2):145-150. [5 human farmers]

Symmers WSC, 1960. Leishmaniasis acquired by contagion: a case of marital infection in Britain. *Lancet* 1:127-132.

Quinnel RJ, Courtenay O, 2009. Transmission, reservoir hosts and control of zoonotic visceral leishmaniasis. *Parasitology* 136(14):1915-1934.

Rosypal AC, Lindsay DS, 2005. Non-sandfly transmission of a North American isolate of *Leishmania infantum* in experimentally infected Balb/c mice. *J Parasitol* 91(5):1113-1115. [both sexual and congenital leishmanial transmission shown in laboratory mice]

Congenital, Parent-to-Offspring Infection:

Banerji D. 1955. Possible congenital infection of kala-azar. J Indian Med Assoc. 24(11):433-435.

Bialek R, Knobloch J. 1999. Parasitic infections in pregnancy and congenital protozoan infections. Part I.: Protozoan infections]. [Article in German] Z Geburtshilfe Neonatol 203(2):55-62.

Blanc C, Robert A. 1984. [5th case of congenital kala-azar][Article in French] Presse Med. 13(28):1751.

Bogdan C, Schonian G, Banuls AL, Hide M, Pratlong F, Lorenz E, Rollinghoff M, Mertens R. 2001. Visceral leishmaniasis in a German child who had never entered a known endemic area: case report and review of the literature. Clin Infect Dis 32(2):302-306.

Castel Y, Chastel C, Le Moigne C, Simitzis AM, Le Fur JM. 1982. [Autochthonous kala-azar (author's transl)][Article in French] Arch Fr Pediatr. 39(2):97-98.

Couvreur J, Desmonts G. 1977. [Parasitic pathology of the fetus] [Article in French] Rev Prat 27(11):647-8, 653-658.

De Raadt P. 1985. [Congenital trypanosomiasis and leishmaniasis] [Article in French] Arch Fr Pediatr. 42 Suppl 2:925-927.

Diaz-Espineira MM, Slappendel RJ, 1997. A case of autochthonous canine leishmaniasis in the Netherlands. *Vet Q* 19(2):69-71.

Dubey JP, Rosypal AC, Pierce V, Scheinberg SN, Lindsay DS. 2005. Placentitis associated with leishmaniasis in a dog. J. Am. Vet. Med. Assoc. 227:12661269.

Elamin A, Omer MI. 1992. Visceral leishmaniasis in a 6-week-old infant: possible congenital transmission. Trop Doct. 22(3):133-135.

Eltoum IA, Zijlstra EE, Ali MS, Ghalib HW, Satti MM, Eltoum B, el-Hassan AM. 1992. Congenital kala-azar and leishmaniasis in the placenta. Am J Trop Med Hyg 46(1):57-62.

Figueiro-Filho EA, Duarte G, El-Beitune P, Quintana SM, Maia TL. 2004. Visceral leishmaniasis (kala-azar) and pregnancy. Infect Dis Obstet Gynecol 12(1):31-40.

Gaskin AA, Schantz P, Jackson J, Birkenheuer A, Tomlinson L, Gramiccia M, Levy M, Steurer F, Kollmar E, Hegarty BC, Ahn A, Breitschwerdt EB. 2002. Visceral leishmaniasis in a New York foxhound kennel. J Vet Intern Med. 16(1):34-44.

Gibson-Corley KN, Hostetter JM, Hostetter SJ, Mullin K, Ramer-Tait AE, Boggiatto PM, Petersen CA. 2008. Disseminated Leishmania infantum infection in two sibling foxhounds due to possible vertical transmission. Clin. Vet. J. 49:1005-1008.

Grech V, Vella C, Parascandolo R. 2000. Successful treatment of visceral leishmaniasis in Finnish-type congenital nephrotic syndrome. Pediatr Nephrol 14(5):410-411.

Kaplanski G, Farnarier C, Durand JM, Soubeyrand J, Bongrand P, Kaplanski S. 1991. Leishmaniasis acquired in Belgium. Lancet. 338(8771):885.

Loke YW. 1982. Transmission of parasites across the placenta. Adv Parasitol. 21:155-228.

Mandanti F, Sozzi S. 1995. Isolation of *Leishmania* from a newborn puppy. Trans. R. Soc. Trop. Med. Hyg. 89(4): 402.

Meinecke CK, Schottelius J, Oskam L, Fleischer B. 1999. Congenital transmission of visceral leishmaniasis (Kala Azar) from an asymptomatic mother to her child. Pediatrics 104(5):e65.

Masucci M., De Majo M, Contarino RB, Borruto G, Vitale F, Pennisi MG, 2003. Canine leishmaniasis in the newborn puppy. Vet. Res. Commun. 27 Suppl. 1: 771-774.

Mittal V, Sehgal S, Yadav TP, Singh VK. 1987. Congenital transmission of kala-azar. J Commun Dis. 19(2):184-185.

Nyakundi PM, Muigai R, Were JB, *Oster CN, Gachihi GS, Kirigi G. 1988. Congenital visceral leishmaniasis: case report. Trans R Soc Trop Med Hyg. 82(4):564.

*Charles N. Oster, MD, was Director, Infectious Diseases Division, Walter Reed Army Medical Center, Washington, D.C.

Pagliano P, Carannante N, Rossi M, Gramiccia M, Gradoni L, Faella FS, Gaeta GB. 2005. Visceral leishmaniasis in pregnancy: a case series and a systematic review of the literature. J Antimicrob Chemother 55(2):229-233.

Pangrazio KK, Costa EA, Amarilla SP, Cino AG, Silva TMA, Costa LF, Dengues EG, Ruiz Diaz AA, Santos RL. 2009. Tissue distribution of Leishmania chagasi and lesions in transplacentally infected fetuses from symptomatic and asymptomatic naturally infected bitches. Vet. Parasitol. 165(3-4):327-331.

Petersen CA. 2009. New means of canine leishmaniasis transmission in North America: the possibility of transmission to humans still unknown. Interdisciplinary Perspective on Infectious Diseases 2009, Art. ID 802712, 5 pages.

Quinn HE, Ellis JT, Smith NC. 2002. Neospora caninum: a cause of immune-mediated failure of pregnancy? Trends Parasitol 18(9):391-394.

Rab MA, Mahmood MT, Bux D, Hassan M, Hassan K. 1991. Visceral leishmaniasis in a six month old child: is congenital transmission of disease possible? J Pak Med Assoc. 41(8):191-193.

Rosypal AC, Troy GC, Zajac AM, Frank G, Lindsay DS. 2005. Transpacental transmission of a North American isolate of *Leishmania infantum* in an experimentally infected Beagle. J. Parasitol. 91(4):970-972.

Schantz PM, Jackson J, Steurer F, Rooney J, Breitschswerdt E, Barr SC. 2001. Evidence for direct dog-to-dog transmission of visceral leishmaniaisis in the United States. *J Am Soc Trop Med Hyg* 65(3):421-422.

Schantz PM, Steurer F, Duprey Z, Rooney J, Kirchhoff LV, L Rowton E, Jackson J, Gramiccia M, 2004. Emergence of canine visceral leishmaniasis in North America, 2000-2003. *Am J Trop Med Hyg* 71(4):44. [Copy in Appendix E.]

Sharma R, Bahl L, Goel A, Upadhaya A, Kaushik SL, Sharma RL, Gupta A. 1996. Congenital kala-azar: a case report. J Commun Dis 28(1):59-61.

Sheikha A. 2004. Dyserythropoiesis in 105 patients with visceral leishmaniasis. Lab Hematol 10(4):206-211.

Yadav TP, Gupta H, Satteya U, Kumar R, Mittal V. 1989. Congenital kala-azar. Ann Trop Med Parasitol. 83(5):535-537.

APPENDIX H

Fifty-three (53) Peer-reviewed Science Journal Articles Reporting Neoplasms/Cancer: *Leishmania* Association

Akcali C, Baba M, Inaloz S, Seckin D, Uzun S. 2008. Cutaneous leishmaniasis mimicking squamous cell carcinoma. *Ann Acad Med* 37(5):435-436.

Albanese F, Poli A, Millanta F, Abramo F. 2002. Primary cutanbeous extragenital canine transmissible venereal tumor with *Leishmania*-laden neoplastic cells: a further suggestion of histiocytic origin? *Vet Dermatol* 13(5):243-246.

Bialek R. 2005. [Parasitic diseases in pediatric cancer patients][Article in German] *Klin Padiatr* 217(Suppl 1):S85-S90.

Boer A, Blodorn-Schlicht N, Wiebels D, Steinkraus V, Falk TM. 2006. Unusual histopathological features of cutaneous leishmaniasis identified by polymerase chain reaction specific for *Leishmania* on paraffin-embedded skin biopsies. *Br J Dermatol* 155(4):815-819.

[Differential diagnosis includes malignant epithelial neoplasms, lymphoma...]

Boutros N, Hawkins D, Nelson M, Lampert IA, Naresh KN. 2006. Burkitt lymphoma and leishmanisis in the same tissue sample in an AIDS patient. *Histopathology* 48(7):880-881.

Brandonisio O, Fumarola L, Spinelli R, Gradoni L. 2002. Unusual presentation of leishmaniasis as an adrenal cystic mass. *Eur J Clin Microbiol Infect Dis* 21(9):682-683.

Brenner DS, Jacobs SC, Drachenberg CB, Papadimitriou JC, 2000. Isolated visceral leishmaniasis presenting as an adrenal cyst. *Arch Pathol Lab Med* 124(10):1553-1556.

Casado JL, Cuesta C, Sanchez JA, Guerrero A, 1998. Solitary pulmonary nodule due to *Leishmania* in a patient with AIDS. *Clin Inf Dis* 26(2):532-534.

Casolari C, Guaraldi G, Pecorari M, Tamassia G, Cappi C, Fabio G, Cesinaro AM, Piolini R, Rumpianesi F, Presutti L. 2005. A rare case of localized mucosal leishmaniasis due to *Leishmania infantum* in an immunocompetent Italian host. *Eur J Epidemiol* 20(6):559-561. [laryngeal tumor]

Castellano VM, Rodriguez-Peralto JL, Alonso S, Gomez-De la Fuente E, Ibarrola C, 1999. Dermatofibroma parasitized by *Leishmania* in HIV infection: a new morphologic expression of dermal kala azar in an immunodepressed patient. *J Cutan Pathol* 26(10):516-519.

Castro Coto A, Hidalgo Hidalgo H, Solano Aguilar E, Coto Chacon F, 1987. [Leishmaniasis of the genital organs.][Article in Spanish] *Med Cut Ibero Lat Am* 15(2):145-150. [5 human farmers]

Catone G, Marino G, Poglayen G, Gramiccia M, Ludovisi A, Zanghi A. 2003. Canine transmissible venereal tumor parasitized by *Leishmania infantum*. *Vet Res Commun* 27(7):549-553.

Dereure J, Duong Thanh H, Lavabre-Bertrand T, Cartron G, Bastides F, Richard-Lenoble D, Dedet JP. 2003. Visceral leishmaniasis. Persistence of parasites in lymph nodes after clinical cure. *J Infect* 47(1):77-81. [drug treatment for leishmaniasis but with lymphoma]

Eholie SP, Tanon AK, Folquet-Amorissani M, Doukoure B, Adoubryn KD, Yattara A, Bissagnene E. 2008. [Three new cases of visceral leishmaniasis in Cote d'Ivoire][Article in French] *Bull Soc Pathol Exot* 101(1):60-61. [Note two patients had chronic lymphoid leukaemia or Burkitt lymphoma.]

Fakhar M, Asgari Q, Motazedian MH, Monabati A. 2008. Mediterranean visceral leishmaniasis associated with lymphoblastic leukemia (ALL). *Parasitol Res* 103(2):473-475.

Fiorini M, Messina MF, Barracchia A, 2002. Peripheral intramonocytotic and intraneutrophil leishmaniasis observed in a chronic myelomonocytic leukemia (CMMoL) patient. *Haematologica* 87(8):EIM21.

Friedman R, Hanson S, Goldberg LH, 2003. Squamous cell carcinoma arising in a *Leishmania* scar. *Dermatol Surg* 29(11):1148-1149.

Gonzalez-Beato MJ, Moyano B, Sanchez C, Gonzalez-Beato MT, Perez-Molina JA, Miralles P, Lazaro P, 2000. Kaposi's sarcoma-like lesions and other nodules as cutaneous involvement in AIDS-related visceral leishmanasis. *Br J Dermatol* 143(6):1316-1318.

Grevot A, Jaussaud Hugues P, Marty P, Pratlong F, Ozon C, Haas P, Breton C, Bourdoiseau G, 2005. Leishmaniosis due to *Leishmania infantum* in a FIV and FelV positive cat with squamous cell carcinoma diagnosed with histological, serological and isoenzymatic methods. *Parasite* 12(3):271-275.

Kamel AH, 1945. Lymphoblastic reticulosarcoma of the orbit. *Bull Ophthalmol Soc Egypt* 38:47-49.

Hagenah GC, Wundisch T, Eckstein E, Zimmermann S, Holst F, Grimm W, Neubauer A, Lohoff M. 2007. [Sepsis-like disease in an immunocompromised patient with a travel history to Mallorca] [Article in German] *Internist (Berl)* 48(7):727-730. [immunoblastic B-cell lymphoma in intestine]

Kawakami A, Fukunaga T, Usui M, Asaoka H, Noda M, Nakajima T, Hashimoto Y, Tanaka A, Kishi Y, Numano F. 1996. Visceral leishmaniasis misdiagnosed as malignant lymphoma. *Internal Med* 35(6): 502-506.

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APPENDIX I

Ninety (90) Peer Reviewed Science Journal Articles Reporting Ocular Pathology in Leishmanial Infections of Humans And Dogs.

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